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United States District Court,
E.D. Pennsylvania.

In re AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION.
This Document Applies to:
Amjad Faheem v. GlaxoSmithKline, LLC
Marvin Rainey v. GlaxoSmithKline, LLC

MDL No. 1871. | No. 07–MD–01871. | Civil Action Nos. 11–695, 11–3031. | Aug. 7, 2012.

Opinion

RUFE, District Judge.

***1** Plaintiffs in these cases filed suit alleging that they suffered heart-related injuries caused by their ingestion of the drug Avandia. Defendant, GlaxoSmithKline, LLC ("GSK"), has filed motions for summary judgment, contending that Plaintiffs' claims are barred by the applicable statutes of limitations.[1] Plaintiffs, through the Plaintiffs' Steering Committee ("PSC"), oppose the motions and have moved for additional discovery pursuant to Federal Rule of Civil Procedure 56(d).[2]

I. BACKGROUND

Plaintiff Marvin Rainey, a resident of Tennessee, began using Avandia in 1999 and suffered a heart attack in 2000; Plaintiff Amjad Faheem, a resident of Kentucky, began using Avandia in 2001 and suffered a heart attack in 2004. Both Plaintiffs filed suit in 2011, alleging that their use of Avandia caused their injuries. Avandia, the brand name for rosiglitazone maleate, was approved by the Food and Drug Administration in 1999 and is manufactured by Defendant GSK. Avandia is a member of a class of drugs known as thiazolidinediones ("TZDs"), used to manage non-insulin-dependent diabetes, or Type 2 diabetes.

Defendant GSK seeks summary judgment on the statue of limitations as to these two Plaintiffs, but also seeks significantly broader relief. Specifically, GSK seeks to establish a "bar date," i.e., the date by which any plaintiffs may be presumed as a matter of law to have been on notice of a possible link between Avandia and their injuries, and therefore to pursue any tort claims. GSK argues that for plaintiffs alleging heart-related injuries from use of Avandia, the bar date is November 14, 2007.

II. STANDARD OF REVIEW

Upon motion of a party, summary judgment is appropriate if "the materials in the record" show "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[3] Summary judgment may be granted only if the moving party persuades the district court that "there exists no genuine issue of material fact that would permit a reasonable jury to find for the nonmoving party."[4] A fact is "material" if it could affect the outcome of the suit, given the applicable substantive law.[5] A dispute about a material fact is "genuine" if the evidence presented "is such that a reasonable jury could return a verdict for the nonmoving party."[6]

In evaluating a summary judgment motion, a court "must view the facts in the light most favorable to the non-moving party," and make every reasonable inference in that party's favor.[7] Further, a court may not weigh the evidence or make credibility determinations.[8] Nevertheless, the party opposing summary judgment must support each essential element of the opposition with concrete evidence in the record.[9] "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted."[10] This requirement upholds the "underlying purpose of summary judgment [which] is to avoid a pointless trial in cases where it is unnecessary and would only cause delay and expense ."[11] Therefore, if, after making all reasonable inferences in favor of the non-moving party, the court determines that there is no genuine dispute as to any material fact, summary judgment is appropriate.[12]

***2** Plaintiffs have filed a motion for additional discovery pursuant to Rule 56(d), which is "the proper recourse of a party faced with a motion for summary judgment who believes that additional discovery is necessary before he can adequately respond to that motion."[13] A properly filed motion must be accompanied by "a supporting affidavit detailing what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained."[14]

III. DISCUSSION

A. Applicable Law

EXHIBIT
I

The rules of the Judicial Panel on MultiDistrict Litigation allow cases to be filed directly in this District and made part of the Avandia MDL, which Plaintiffs in these cases did.[15]The Court must determine whether to apply Pennsylvania law or the law of Plaintiffs' home states. The Court has concluded, as have other MDL courts, that such cases should be governed by the law of the states where Plaintiffs received treatment and prescriptions for Avandia.[16]This ruling will promote uniform treatment between those Plaintiffs whose cases were transferred into the MDL from their home states and those Plaintiffs who filed directly into the MDL. This holding is also consistent with Pennsylvania's choice-of-law rules, because "Pennsylvania applies a flexible rule which permits analysis of the policies and interests underlying the particular issue before the court and directs courts to apply the law of the state with the 'most interest in the problem.' "[17] In personal injury cases, that is the state where the injury occurred.[18]

Faheem's home state, Kentucky, employs a one year statute of limitations for personal injury cases.[19]Kentucky law also recognizes the "discovery rule," under which "[a] cause of action will not accrue ... until the plaintiff discovers or in the exercise of reasonable diligence should have discovered not only that he has been injured but also that his injury may have been caused by the defendant's conduct."[20]Reasonable diligence requires that the plaintiff be "as diligent as the great majority of persons would [be] in the same or similar circumstances...."[21]

Rainey's home state, Tennessee, also has a one-year statute of limitations in personal injury cases,[22] with the cause of action generally accruing on the date of the injury.[23]Tennessee also recognizes the discovery rule which tolls the statute of limitations until "one discovers, or in the exercise of reasonable diligence should have discovered, both (1) that he or she has been injured by wrongful or tortious conduct and (2) the identity of the person or persons whose wrongful conduct caused the injury."[24]This only requires that the plaintiff be aware of those facts sufficient "to place a reasonable person on notice that the injury was the result of the wrongful conduct of another."[25]

B. 2007 Evidence of a Possible Link between Avandia Use and Heart–Related Injuries

1. The Nissen Study and FDA Action

***3** After conducting a meta-analysis study, Dr. Steven Nissen concluded that use of Avandia was associated with an increased risk of heart attack. Specifically, the Nissen study found that Avandia increased the risk of myocardial infarction by 43%, a statistically significant result.[26]The New England Journal of Medicine published the peer-reviewed Nissen study on May 21, 2007. In response to the Nissen study's publication, the American College of Cardiology, American Diabetes Association, and American Heart Association issued a statement expressing concern and advising patients with diabetes to speak with their physicians.[27]At a meeting in July 2007, the Food and Drug Administration Advisory Committee voted 20–3 that "available data support a conclusion that Avandia increases cardiac ischemic risk," but did not act at that time to restrict the availability of Avandia.[28] However, the FDA did require that GSK revise the product label for Avandia, and GSK agreed to include within a black box warning the statement that "Avandia was not recommended for any patient with symptomatic heart failure," to add a summary of the results of an integrated data set from 42 clinical trials regarding risk of myocardial ischemic events, and to include more detailed results in the Warnings section in the label.[29]

2. "Dear Healthcare Professional" and "Dear Patient" Letters

From May through November 2007, GSK sent a series of letters to healthcare professionals regarding studies of Avandia and cardiovascular health.[30] These letters discussed various studies, including the Nissen study (and GSK's disagreement with it)[31] as well as regulatory developments with regard to cardiovascular risk and Avandia use, culminating in a November 2007 letter reporting on the label revision. Any physician receiving these letters would be aware that there was concern about cardiovascular health and use of Avandia, although the letters expressed GSK's view that Avandia remained "an important treatment option for physicians" in treating diabetes.[32]On June 1, 2007, GSK also published a "Dear Avandia Patient" letter, which responded to the "recent press coverage about the safety of Avandia" and stated that GSK stood firmly behind Avandia.[33]Plaintiffs have produced evidence that during this same time frame, GSK criticized the Nissen study, and worked to encourage physicians to continue to prescribe Avandia.[34]

3. Media Reports

The publication of the Nissen Study generated substantial interest in the media. Significantly, in the days following the publication, television news programs highlighted the findings of the Nissen report, in several instances as the lead story on the national evening broadcast.[35]These reports summarized the findings of the Nissen study and also noted that GSK "strongly disagrees with the

conclusions ... and says other studies prove the drug's safety."[36]During the summer and fall of 2007, national and local newspapers published articles of varying depth and prominence discussing reported risks of Avandia use.[37]Many of these news reports included GSK's assurances that Avandia was safe and effective. The media also reported the actions of the FDA Advisory Committee, describing it in at least one report as sending a "mixed message" to Avandia patients.[38]The November 2007 label revision generated still more news stories, which included the information that the FDA had decided to keep Avandia on the market and noted that the evidence of an increased risk of cardiovascular events was "inconclusive."[39]

C. The Cumulative Effect of 2007 Events Triggered the Duty to Investigate

***4** The evidence shows that the events described above were regarded as significant by physicians, patients, and attorneys. By August 2007, Avandia prescriptions had fallen by 45%; by November 2007, sales had fallen 54%.[40] This MDL was formed in 2007 as a result of numerous lawsuits filed nationwide that year.

The question then becomes, did all of these events suffice, as a matter of law, to put on notice those who had suffered heart-related injuries that Avandia could be to blame and trigger a duty to investigate? The extensive media reports "indicate what was in the public realm at the time, not whether the contents of those articles were in fact true."[41]What was in the public realm throughout the second half of 2007 linked Avandia use with the possibility of heart-related illness, although the reports certainly did not reach an unqualified conclusion in that regard.[42]

The Court concludes that a reasonable person who knew that he or she had suffered cardiovascular injury and had taken Avandia would have been put on notice by the end of 2007 of the need to investigate a possible link between Avandia and the injury. Plaintiffs argue strenuously that GSK concealed information regarding the risks of Avandia and continued to downplay the seriousness of the risks until 2010, and that in August 2007, GSK argued to physicians that the "totality of evidence" showed "[n]o increased risk of [cardiovascular events] vs. oral antidiabetic agents."[43]Accepting Plaintiffs' argument as true for purposes of the motions for summary judgment, Plaintiffs in these cases *had already suffered heart attacks, and knew that they had done so.*A reasonable person who had suffered a heart attack, and who had taken Avandia, as Plaintiffs here did, would have been on notice by the end of 2007 to investigate a possible link between the Avandia use and the heart attack.[44]Similarly, Plaintiffs' arguments of fraudulent concealment miss the mark. The issue of whether GSK should have disclosed more information or disclosed it sooner does not affect what information became available in 2007.

D. Plaintiffs' Rule 56(d) Motion

Plaintiffs have moved for time to take additional discovery, including individualized discovery as to what Plaintiffs and their physicians knew and when, and extensive discovery that essentially relates to GSK's alleged fraudulent concealment. The Court finds that these are not typical cases where summary judgment is sought before discovery: during the course of the MDL, many hundreds of thousands of pages of documents have been produced, and Plaintiffs have not demonstrated that more is necessary on the issues discussed herein. Further, discovery as to the personal circumstances of Plaintiffs is not required because the evidence presented demonstrates as a matter of law that the information available both to the general public and to treating physicians throughout 2007 should have put a reasonable person on notice to investigate the possible link between a heart attack already suffered and use of Avandia.[45]

E. Limitations of the Court's Ruling

***5** The Court holds that under the laws of Tennessee and Kentucky, a reasonable person who knew that he or she had suffered a heart-related injury after taking Avandia was on notice by the end of 2007[46] to investigate the possibility of a link between Avandia and their injury so as to start the statute of limitations running on tort claims alleging personal injury. This ruling does not address Avandia patients who suffered other injuries, such as stroke; nor does it address any other claims asserted against GSK. The Court is not ruling at this time on whether GSK concealed evidence of the risks of Avandia use. The Court also notes that the law of certain states may have a different view of when a claim is tolled.

IV. CONCLUSION

The Court holds that a reasonable person who knew that he or she had suffered a heart-related injury after taking Avandia was on notice to investigate the possible link between the injury and Avandia use by December 31, 2007. Because Plaintiffs did not file their personal-injury claims within the applicable statute of limitations, GSK's Motions for Summary Judgment will be granted, and those claims will be dismissed. An appropriate order will

be entered.

Footnotes

1 GSK filed the Motion for Summary Judgment in five cases. By notice dated February 28, 2012, GSK withdrew the motion in the case of *Randall v. GlaxoSmithKline, LLC,* Civil Action No. 10–4861, as the case became subject to a pending settlement agreement. By letter dated June 6, 2012, GSK advised the Court that an agreement in principle had been reached to settle the cases of *Bonn v. GlaxoSmithKline, LLC,* Civil Action No. 11–2734, and *Estate of Henry v. GlaxoSmithKline,* Civil Action No. 10–4080.

2 By Memorandum and Orderdated September 7, 2011, the Court denied motions to dismiss based on the statute of limitations in 60 cases. Defendant GlaxoSmithKline, LLC ("GSK") filed motions for partial reconsideration, seeking again to dismiss all or part of 49 of these cases; those motions were also denied. In the earlier rulings, the Court held that the Court could not make a determination in the context of a motion to dismiss, but required an evidentiary record.

3 Fed.R.Civ.P. 56(a), (c)(1)(A).

4 *Miller v. Ind. Hosp.,* 843 F.2d 139, 143 (3d Cir.1988).

5 *See Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986).

6 *Id.*

7 *Hugh v. Butler Cnty. Family YMCA,* 418 F.3d 265, 267 (3d Cir.2005).

8 *Boyle v. County of Allegheny,* 139 F.3d 386, 393 (3d Cir.1998).

9 *Celotex Corp. v. Catrett,* 477 U.S. 317, 322–23 (1986).

10 *Anderson,* 477 U.S. at 249–50 (citations omitted).

11 *Walden v. Saint Gobain Corp.,* 323 F.Supp.2d 637, 641 (E.D.Pa.2004) (citing *Goodman v. Mead Johnson & Co.,* 534 F.2d 566, 573 (3d Cir.1976)).

12 *Celotex,* 477 U.S. at 322; *Wisniewski v. Johns–Manville Corp.,* 812 F.2d 81, 83 (3d Cir.1987).

13 *Murphy v. Millennium Radio Grp. LLC,* 650 F.3d 295, 309 (3d Cir.2011).Rule 56(d) provides that "[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order."

14 *Doe v. Abington Friends Sch.,* 480 F.3d 252, 257 n. 3 (3d Cir.2007) (internal quotation omitted).

15 JPML Rule 7.2(a) provides that "[p]otential tag-along actions filed in the transferee district do not require Panel action. A party should request assignment of such actions to the Section 1407 transferee judge in accordance with applicable local rules."

16 *See, e.g., In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.,* No. 3:09–MD–2100, 2011 WL 1375011, *5 (S.D.Ill. Apr. 12, 2011) (holding that cases that originated outside of the court's judicial district and that were filed directly into the MDL would be treated as if they were transferred from a judicial district sitting in the state where the case originated).

17 *Specialty Surfaces Int'l v. Cont'l Cas. Co.,* 609 F.3d 223, 229 (3d Cir.2010).

18 *See, e.g., Flamer v. New Jersey Transit Bus Operations, Inc.,* 607 A.2d 260, 264 (Pa.Super.Ct.1992) (internal citation omitted). The Court does note that Pennsylvania has a "borrowing statute," which provides that "[t]he period of limitation applicable to a claim accruing outside this Commonwealth shall be either that provided or prescribed by the law of the place where the claim accrued or by the law of this Commonwealth, whichever first bars the claim."42 Pa. Cons.Stat. Ann. § 5521(b). However, because the Court considers that "direct filed" cases should be treated as if they were filed in the Plaintiffs' home states, the forum-shopping concerns of this statute are not implicated here.

19 *See*Ky.Rev.Stat. § 413.140(1), (1)(a).

20 *R.T. Vanderbilt Co., Inc. v. Franklin,* 290 S.W.3d 654, 659 (Ky.Ct.App.2009) (citing *Louisville Trust Co. v. Johns–Manville Prods. Corp.,* 580 S.W.2d 497, 501 (Ky.1979) (quotation in *Louisville Trust* omitted)); *see also Johnson v. Sandoz Pharm. Corp.,* 24 F. App'x 533, 535–39 (6th Cir.2001) (applying Kentucky law in determining how the discovery rule affected the statute of limitations in products liability case where plaintiff claimed Parlodel led to stroke).

21 *Id.* (citing *Blanton v. Cooper Indus.,* 99 F.Supp.2d 797, 802 (E.D.Ky.2000) (quoting *Sawyer v. Midelfort,* 595 N.W.2d 423, 439 (Wis.1999)) (internal quotations omitted)).

22 *See*Tenn.Code Ann. § 28–3–104(a), (a)(1) ("Actions for ... injuries to the person ...." "shall be commenced within one (1) year ....").

23 Tenn.Code Ann. § 28–3–104(b)(1).

24 *Sherrill v. Souder,* 325 S.W.3d 584, 595 (Tenn.2010).*See also Wyatt v. A–Best, Co., Inc.,* 910 S.W.2d 851, 854 (Tenn.1995); *Potts v. Celotex Corp.,* 796 S.W.2d 678, 680–81 (Tenn.1990) ("[T]he statute [of limitations] is tolled only during the period when the plaintiff had no knowledge at all that the wrong had occurred and, as a reasonable person, was not put on inquiry."); *Teeters v. Currey,* 518 S.W.2d 512, 512–17 (Tenn.1974) (first adopting the discovery rule); *Carter v. Danek Med, Inc.,* 1999 WL 33537317, at *3–4 (W.D.Tenn.1999) (discussing the tolling of the statute of limitations in products liability claims involving spinal surgery).

25 *Id.*

26 *In re Avandia,* No. 07–1871, 2011 WL 13576, at *3 (E.D.Pa. Jan. 4, 2011).

27 GSK Ex. 138.

28 PSC Ex. 124 at 4.

29 GSK Ex. 137.

30 GSK Exs. 130–37.

31 GSK Ex. 130 at 1.

32 *E.g.,* GSK Ex. 137 at 2.

33 Compls. ¶ 55.

34 PSC Exs. 134–42.

35 GSK Exs. 9–19.

36 *See, e.g.,* GSK Ex. 9.

37 GSK Exs. 20–142. GSK also produced a listing of news reports that mentioned Avandia. GSK Exs. 5–6. The Court finds these exhibits of limited use to the Court; a number of the references appear to be to articles mentioning the effect of Avandia issues on GSK's stock price, for example, and do not appear likely to have drawn general notice.

38 GSK Ex. 82 (ABC News transcript, July 31, 2007).

39 *See, e.g.,* GSK Ex. 121 (New York Times article, Nov. 15, 2007).

40 PSC Ex. 128; GSK Rao Decl. Ex. 4.

41 *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Management L.P.,* 435 F.3d 396, 401 n. 15 (3d Cir.2006).

42 Other Courts have set similar limitations periods. *See, e.g .*, *In re Briscoe,* 448 F.3d 201, 220–21 (3d Cir.2006) (in diet drugs litigation, finding that the statute of limitations barred claims after class notifications that followed withdrawal of the drugs from the market); *In re Vioxx Prods. Liab. Litig.,* 522 F.Supp.2d 799, 803 (E.D.La.2007) (finding that the statute of limitations barred claims after extensive publicity following the withdrawal of Vioxx from the market). Other courts have found that the statute of limitations applies even when a drug has not been withdrawn from the market. *See, e.g., In re Zyprexa Prods. Liab. Litig.,* 489 F.Supp.2d 230 (E.D.N.Y.2007).

43 PSC Ex. 126.

44 The Court notes that Type 2 diabetes is not a temporary condition; there is no cure, and patients who were receiving treatment in 2000 would still need to be managing their condition in 2007 (although not necessarily with medication).*See* Mayo Clinic Staff "Type 2 Diabetes" retrieved from http://www.mayoclinic.com/health/type–2–diabetes/DS00585 (last viewed Aug. 1, 2012).

45 In addition, Plaintiffs were not prevented from offering evidence of their individual circumstances, for example, through affidavits.

46 Although GSK argues that the bar date should be November 14, 2007, the Court finds that news coverage of the 2007 label revision continued after that date, and therefore concludes that the last date on which Plaintiffs should have been on notice is December 31, 2007.

2000 WL 223508
United States District Court, M.D. North Carolina.

Dorothy M. BARAUKAS and Karl A. Baraukas,[1]
Plaintiffs,
v.
DANEK MEDICAL, INC., Sofamar Danek Group, Inc., and Warsaw Orthopedic, Inc., Defendants.

No. 6:97CV00613. | Jan. 13, 2000.

MEMORANDUM OPINION AND ORDER

ELIASON, Magistrate J.

Statement of the Case

***1** Plaintiffs filed this action in this Court alleging fraud, civil conspiracy, fraudulent marketing and promotion, negligence per se, negligence, breach of the implied warranty of merchantability, and loss of consortium. They requested actual and punitive damages as a result of these claims. After the filing of the suit, this case, along with numerous other cases, was transferred for consolidated pretrial proceedings to the Eastern District of Pennsylvania. Following proceedings there, the case was returned to this district. All discovery on liability has now concluded and defendants have filed a motion for summary judgment. Despite being notified by this Court of their right to respond to that motion, plaintiffs failed to do so. The time for a response has long since run and the motion is ready for a decision.

Facts

On June 28, 1993, Dorothy Barauskas suffered a back injury while at work. She was diagnosed with "fairly significant spinal stenosis ." (Defendants' Brf., Tab 3, at 2) Conservative treatment followed, and Ms. Barauskas was released from care with a five percent disability of her back in September of 1993.(*Id.,* Tab 4) However, in January of 1994, she suffered further back pain which led to a diagnosis of degenerative disc disease. She was then treated with a back brace which did not alleviate her pain. (*Id.,* Tab 5 at 13-14)

Having exhausted conservative treatments, Ms. Barauskas' doctor, Harlan Daubert, began discussing the possibility of performing spinal fusion surgery with her. According to Dr. Daubert, he discussed the significant risks of the surgery with Ms. Barauskas and her husband and told them that the use of pedicle screws during the surgery was controversial. (*Id.,* Tab 5 at 14-16) Despite these warnings, Ms. Barauskas chose to proceed with the surgery. She admits that Dr. Daubert warned her that the surgery was "experimental or investigational," and that screws, rods and plates were not approved by the FDA for back surgery. (*Id.,* Tab 1 at 14-15) He also told her that there was a risk of continued back pain following surgery and that there were risks and potential complications. (*Id.,* Tab 5 at 16, 19)

Dr. Daubert did perform the spinal fusion surgery on Ms. Barauskas using a pedicle screw device manufactured by defendants. This device was implanted to stabilize her spine and allow fusion to occur. Despite proper placement of the instrumentation, she continued to suffer pain following the surgery. However, Dr. Daubert does not believe that the pedicle screw device was the source of that pain or that the device had malfunctioned. In fact, Dr. Daubert states that x-rays taken in 1997 showed "no evidence of any broken screws or anything other than a solid arthrodesis."(*Id.,* Tab 5 at 17-20)

Summary Judgment Standards

Summary judgment should be granted only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."Fed.R.Civ.P. 56(c). The Court must view the evidence in a light most favorable to the non-moving party. *Pachaly v. City of Lynchburg,* 897 F.2d 723, 725 (4th Cir.1990). When opposing a properly supported motion for summary judgment, the party cannot rest on conclusory statements, but must provide specific facts, particularly when that party has the burden of proof on an issue. *Id.* The mere fact that both parties request summary judgment does not necessarily mean that the material facts are undisputed. *World-Wide Rights Ltd. Partnership v. Combe Inc.,* 955 F.2d 242, 244 (4th Cir.1992)."The summary judgment inquiry thus scrutinizes the plaintiff's

case to determine whether the plaintiff has proffered sufficient proof, *in the form of admissible evidence,* that could carry the burden of proof of his claim at trial."*Mitchell v. Data General Corp.,* 12 F.3d 1310, 1316 (4th Cir.1993) (emphasis added). A mere scintilla of evidence will not suffice. Rather, there must be enough evidence for a jury to render a verdict in favor of the party making a claim. A few isolated facts are not sufficient. *Sibley v. Lutheran Hosp. of Maryland, Inc.,* 871 F.2d 479 (4 th Cir.1989).

***2** Where plaintiffs' claims arise under state law, special rules apply. When state law is unclear, the federal court must rule in such a manner as it appears the highest state court would rule if presented with the issue. Where the state's highest court has not decided the particular issue, the federal court should examine the rulings of the lower state courts. Rulings of the lower courts may be considered as persuasive evidence of state law, but they are not binding on the federal court should it be convinced the highest court would rule to the contrary. *Sanderson v. Rice,* 777 F.2d 902, 903 (4th Cir.1985), *cert.denied,*475 U.S. 1027, 106 S .Ct. 1226, 89 L.Ed.2d 336 (1986). Furthermore, the federal court must rule on state law as it exists, as opposed to surmising or suggesting an expansion of state law. *Burris Chemical, Inc. v. USX Corp.,* 10 F.3d 243 (4th Cir.1993).

Discussion

Before discussing plaintiffs' claims directly, there are three points worthy of comment. First, plaintiffs' civil conspiracy claim was dismissed while the case was in Pennsylvania and that decision was upheld by the Third Circuit Court of Appeals. Therefore, that claim is not before the Court. *In re: Orthopedic Bone Screw Products Liability Litigation,* 193 F.3d 781 (3d Cir.1999). Second, as mentioned above, plaintiffs have failed to respond to defendants' motion for summary judgment. Therefore, under Local Rules 7.3(k) and 56.1(e), the Court may find the motion to be uncontested and grant it without further notice. However, given plaintiffs' pro se status, the Court will act with an abundance of caution and examine the motion closely on its merits. Finally, it is worth noting that this is not the first case of its type to be decided. As set out in defendants' brief, many decisions in similar cases, including some in this state and even this district, have been rendered in favor of defendants. To the extent that they raise issues similar to the ones in the present case, those decisions will have no small impact on the outcome of defendants' motion.

Causation

Defendants' first argument in favor of summary judgment is that plaintiffs have failed to show that defendants' product caused any of Ms. Barauskas' alleged back problems. There is no question that causation is an essential element of all of plaintiffs' remaining claims and that failure to supply sufficient proof of causation would compel summary judgment for defendants on all claims. *SeeLester v. Danek Medical, Inc.,* No. 2:96CV1006, (M.D.N.C. Apr. 16, 1999) (causation an essential element of fraud, negligence, breach of implied warranty); *Cheek v. Danek Medical, Inc.,* No. 6:96CV00995 (M.D.N.C. Mar. 9, 1999) (causation an essential element of fraud, negligence per se, breach of implied warranty, loss of consortium); *Driggers v. Sofamor, S.N.C.,* 44 F.Supp.2d 760 (M.D.N.C.1998) (causation an essential element of fraudulent marketing and promotion, negligence per se, negligence, breach of implied warranty, loss of consortium); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23, 106 S.Ct. 2548, 2552, 91 L.Ed.2d 265 (1986) (failure to establish an essential element of a claim will result in summary judgment). The only remaining question then is whether plaintiffs have produced sufficient evidence to allow a jury to find that Ms. Bauraskas' back was injured by defendants' pedicle screw device.

***3** With certain claims, the issue of causation may be sent to the jury solely on the basis of lay testimony. However, with complicated medical injuries, expert medical testimony is required in order to allow a jury to find for a plaintiff on the issue of causation. *Click v. Pilot Freight Carriers, Inc.,* 300 N.C. 164, 167, 265 S.E.2d 389, 391 (1980). As previously noted by this Court, North Carolina " 'courts have long held the cause of back injuries can only be established by expert medical testimony." ' *Lester,* slip op. at 7,*quoting,Cherry v. Harrell,* 84 N.C.App. 598, 601, 353 S.E.2d 433, 435,*disc.rev.denied,*320 N.C. 167, 358 S.E.2d 49 (1987).

In the present case, the time for designating medical experts is long past. Plaintiffs have failed to do so and, therefore, are left with no expert testimony on causation. Further, the only medical testimony in the record was provided by Ms. Barauskas' physician, Dr. Daubert. As set out previously, his clear testimony is that he does not believe that the pedicle screw device is the cause of Ms. Barauskas' back pain. Given plaintiffs' failure to present expert medical testimony on causation and the testimony in the record which contradicts their claims, this Court finds that summary judgment for defendants is

appropriate on all of plaintiffs' claims.

In addition to its causation argument which would cover all of plaintiffs' claims, defendants also make arguments which would pertain to only some of plaintiffs' claims. Several of these are worthy of mention or short discussion.

Product Defect

Even assuming that plaintiffs could establish causation, their claim for negligence would fail because of a lack of evidence establishing that defendants' product is defective. In a product liability action, a plaintiff must show that the product manufactured by the defendant was defective at the time it left the defendant's plant, and that the defendant was negligent in designing the product, selecting materials for it, assembling it, or inspecting it. *Penland v. BIC Corp.,* 796 F.Supp. 877, 883-84 (W .D.N.C.1992), *citing,Jolley v. General Motors Corp.,* 55 N.C.App. 383, 285 S.E.2d 301 (1982); *Cockerham v. Ward,* 44 N.C.App. 615, 262 S.E.2d 651,*rev.denied,*300 N.C. 195, 269 S.E.2d 622 (1980). These showings must be established by evidence beyond speculation or conjecture. *Id.citing,Jolley* at 385, 285 S.E.2d 301.

Here, plaintiffs have introduced no evidence to show that the pedicle screw device was defectively designed or manufactured or even that it malfunctioned. In fact, the implanting surgeon, Dr. Daubert, has testified that the device he placed in Ms. Barauskas performed as he intended it to and that he never saw any malfunction or problem with the device. Also, as noted previously, x-rays taken in September of 1997 showed that the device was intact. Clearly, plaintiffs have failed to establish that defendants' product was defective and her negligence claim must be dismissed.

Learned Intermediary Doctrine

***4** Defendants contend that to the extent that plaintiffs' fraud, negligence, and breach of warranty claims are premised on a failure to warn Ms. Barauskas of the risks associated with implantation of the pedicle screw device, they are barred by the learned intermediary doctrine. According to the learned intermediary doctrine, where a defendant manufactures a product which is dispensed to patients by doctors, rather than directly, the defendant has a duty to warn only the doctor, rather than the patients of any risks associated with the product's use. It is assumed that the doctors will pass along appropriate information to their patients. There are indications that North Carolina courts would adhere to the learned intermediary doctrine. *SeeFoyle By and Through McMillian v. Lederle Laboratories,* 674 F.Supp. 530, 535-36 (E.D.N.C.1987), *citing,Holley v. Burroughs Welcome Co.,* 74 N.C.App. 736, 330 S.E.2d 228 (1985), *aff'd,*318 N.C. 352, 348 S.E.2d 772 (1986). In another bone screw case, one court stated that a bone screw manufacturer is not liable even if it provides inadequate information as long as the plaintiff's physician independently knew of the risks. *Talley v. Danek Medical, Inc.,* 7 F.Supp.2d 725, 730 (E.D.Va.1998), *affirmed,*179 F.3d 154 (4th Cir.1999).

In the present, Dr. Daubert, an orthopedic surgeon with extensive training and experience with lumbar fusion surgery, has stated that he did warn Ms. Bauraskas of the "significant risks" of her surgery. He also informed her that the use of the pedicle screw device was experimental and controversial. Dr. Daubert's testimony shows that the status of the pedicle screw device with the FDA would not have influenced his opinion of the usefulness of the device as demonstrated by other sources of information. (Defendants' Brf., Tab 5 at 10-11) Accordingly, the uncontradicted evidence shows that Dr. Daubert formed an independent opinion of the efficacy of the pedicle screw device and passed that opinion on to Ms. Barauskas. To the extent that they rely on defendants' failure to warn her of the risks of the pedicle screw device, plaintiffs' claims fail under the learned intermediary doctrine.

FDA Findings

Plaintiffs' fraud and negligence per se claims are premised on alleged misrepresentations made to the FDA by defendants concerning their pedicle screw devices. However, the FDA has investigated this alleged fraud and concluded that it was not defrauded. (*Id.,* Tab 25, at 40028-30) At least one other court has used this as a basis for dismissing bone screw fraud claims.*Estep v. Danek Medical, Inc.,* No. 1:96CV2580, (N.D. Ohio Oct 5, 1998) (Defendants' Brf., Tab 28) The FDA's conclusions serve as an additional reason for dismissing plaintiffs' fraud and negligence per se claims.[2]

Derivative Claims

Two of plaintiffs' causes of action-punitive damages and loss of consortium-are derivative of their other claims. Because the other claims are being dismissed, these claims fail as well and they too must be dismissed.

***5** IT IS THEREFORE ORDERED that defendants' motion for summary judgment (docket no. 24) is granted and that this action be, and the same hereby is, dismissed.

Parallel Citations

Prod.Liab.Rep. (CCH) P 15,805

Footnotes

1 It appears that plaintiffs' last name is actually Barauskas rather than Baraukas.

2 Regarding the negligence per se claim, defendants raise two additional arguments. First, they contend that the claim should be dismissed as a disguised attempt to enforce the Food, Drug and Cosmetic Act (hereinafter FDCA) through a private cause of action which that act prohibits. This argument appears to have merit and has been used to dismiss similar claims. *Hill v. Danek Medical, Inc.,* No. 4:96-CV-177-H1, 1998 U.S. Dist. LEXIS 21749 (E.D.N.C. Sept. 10, 1998). Defendants also contend that the FDCA is too vague to act as a standard of care which could be used to establish negligence per se. This seems to have some support in North Carolina law. *See*Goodman v. Wenco Foods, Inc., 333 N.C. 1, 423 S.E.2d 444 (1992).

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United States District Court, E.D. North Carolina, Western Division.

Jimmy EARP and Patricia Earp, Plaintiffs,
v.
NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.

No. 5:11–CV–680–D. | Sept. 11, 2013.

Attorneys and Law Firms

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ORDER

JAMES C. DEVER III, Chief Judge.

***1** On September 1, 2006, Jimmy Earp ("Earp") and Patricia Earp (collectively, "plaintiffs") and others filed a complaint alleging various claims against Novartis Pharmaceuticals Corporation ("Novartis" or "defendant") arising from osteonecrosis of the jaw ("ONJ") allegedly caused by use of Aredia and Zometa, two prescription bisphosphonate medications that Novartis produced and sold. *Earp v. Novartis Pharm. Corp.,* No. 5:06–CV–350–D, [D.E. 1] (E.D.N.C. Sept. 1,2006). The action was transferred to the United States District Court for the Middle District of Tennessee for Multi–District Litigation ("MDL") proceedings. *See id,* [D.E. 1112] (E.D.N.C. Nov. 6, 2006); *In re Aredia & Zometa Prods. Liab. Litig.,* No. 3:06–md–1760 (M.D.Tenn.). After discovery proceedings and severance of the Earps' case, the MDL court transferred the case back to this court for further proceedings, including (if needed) a trial [D.E. 44]. On November 19, 2012, the court entered a scheduling order for pretrial motions [D.E. 60].

On November 8, 2012, plaintiffs moved to amend the complaint and filed a supporting memorandum and exhibit [D.E. 55–56]. On December 3, 2012, Novartis responded in opposition [D.E. 64]. On December 20, 2012, Novartis moved to exclude certain expert testimony as either irrelevant or unreliable pursuant to *Daubert v. Merrel Dow Pharm., Inc.,* 509 U.S. 579 (1993).*See* [D.E. 66, 68, 70, 72, 74, 76]. On January 22, 2013, plaintiffs responded in opposition to the motions to exclude expert testimony [D.E. 80, 8283] and filed a cross motion seeking to collaterally estop defendant's motions to exclude [D.E. 84]. Novartis replied on February 4, 2013 [D.E. 85–90] and responded to plantiffs' estoppel request on February 15, 2013 [D.E. 93]. On December 20, 2012, Novartis moved for summary judgment [D.E. 78] and filed a supporting memorandum and exhibits [D .E. 79]. Plaintiffs responded in opposition [D.E. 81], and Novartis replied [D.E. 91]. As explained below, the court denies plaintiffs' motion to amend, denies defendant's *Daubert* motions, and grants in part and denies in part defendant's motion for summary judgment.

I.

As for plaintiffs' motion to amend the complaint, plaintiffs filed the motion on November 8, 2012, approximately 21 months after the close of fact discovery and 18 months after the deadline for filing dispositive motions. *See* Scheduling Order [D.E. 27] 4. The scheduling order did not set a deadline for filing amended pleadings. *See id.*

The court should freely give leave to amend "when justice so requires." Fed.R.Civ.P. 15(a)(2). However, when a party seeks to amend a complaint after the date set forth in a scheduling order for such motions, the party must establish good cause under Rule 16. *See Nourison Rug Corp. v. Parvizian,* 535 F.3d 295, 298–99 (4th Cir.2008); *see*Fed.R.Civ.P. 16(b)(4). Although the scheduling order did not set a deadline for filing amended pleadings, the deadline for filing dispositive motions necessarily implied a deadline for amended pleadings. After all, any new pleadings would require the court to amend the scheduling order to allow Novartis to file responsive dispositive motions and to conduct any necessary discovery. Thus, plaintiffs must meet the good cause standard of Rule 16.

***2** Plaintiffs seek to add a claim under North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA"), N.C. Gen.Stat. § 75–1. Plaintiffs offer no explanation for the late addition of the claim one and a half years after the

deadline for dispositive motions even though the proposed new claim allegedly is "based completely on previously plead[ed] and discovered facts."Pls.' Mem. Supp. Mot. Amend [D.E. 56] 2.

Plaintiffs have failed to show good cause under Rule 16. *See Nourison Rug Corp.,* 535 F.3d at 298–99.Moreover, adding the UDTPA claim would prejudice Novartis and further delay the case. Thus, even if the court applied only Rule 15, the court would still deny the motion due to prejudice. *See id.* at 298 (describing Rule 15 standard). Accordingly, the court denies the motion to amend.

II.

Novartis has filed a number of motions seeking to exclude the testimony of plaintiffs' experts under *Daubert* and Federal Rule of Evidence 702. Specifically, Novartis filed motions to exclude (1) testimony of Dr. Robert Marx regarding causation, Novartis's state of mind, Novartis's operation of clinical trials, and the efficacy of certain dental treatments [D.E. 66]; (2) testimony of plaintiffs' regulatory expert Dr. Suzanne Parisian [D.E. 68]; (3) testimony of Dr. Keith Skubitz about ONJ, the drafting and approval of Aredia and Zometa labels, FDA dosing information, and the efficacy of preventative dentistry for patients using Aredia and Zometa [D.E. 70]; (4) testimony of Dr. James Vogel [D.E. 72]; (5) testimony regarding specific causation of plaintiff Earp's ONJ by retained expert Dr. Frederick Nance and plaintiff Earp's treating physicians Dr. George Blakey, Dr. Mark Yoffe, Dr. Alan Kritz, Dr. Daniel Petrocella, and Dr. Steven Davis [D.E. 74]; and (6) general causation testimony of Dr. Wayne Ray [D.E. 76].

Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed.R.Evid. 702. *Daubert* clarifies that Rule 702"assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand."509 U.S. at 597.The court recognizes that "Rule 702 was intended to liberalize the introduction of relevant expert evidence," but that "expert witnesses have the potential to be both powerful and quite misleading."*Cooper v. Smith & Nephew, Inc.,* 259 F.3d 194, 199 (4th Cir.2001) (quotation omitted).

The proponent of the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *Id.* A district court has broad latitude in determining whether to admit proposed expert testimony.*United States v. Gastiaburo.* 16 F.3d 582, 589 (4th Cir.1994).

***3** Courts have distilled Rule 702's requirements in two crucial inquiries: whether the proposed expert testimony is relevant and whether it is reliable. *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 141 (1999); *Daubert,* 509 U.S. at 589; *United States v. Forrest,* 429 F.3d 73, 80 (4th Cir.2005). To be relevant, the proposed expert testimony must be helpful to the trier of fact. *See Daubert,* 509 U.S. at 591–92."Testimony from an expert is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror."*Kopf v. Skyrm,* 993 F.2d 374, 377 (4th Cir.1993); *accord Koger v. Norfolk S. Ry. Co.,* No. 1:08–0909, 2010 WL 692842, at *1 (S.D.W.Va. Feb. 23, 2010) (unpublished).

"[T]he test of reliability is flexible and the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination."*United States v. Wilson,* 484 F.3d 267, 274 (4th Cir.2007) (quotation omitted); *see Kumho Tire.* 526 U.S. at 141–42.A witness may qualify to render expert opinions in any one of the five ways listed in Rule 702: knowledge, skill, experience, training, or education. *See Kumho Tire.* 526 U.S. at 147.When a party challenges an expert's qualifications, " 'the test for exclusion is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered.' " *Kopf,* 993 F.2d at 377 (quoting *Thomas J. Kline, Inc. v. Lorillard, Inc.,* 878 F.2d 791, 799 (4th Cir.1989)). "In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful; the particular factors will depend upon the unique circumstances of the expert testimony involved." *Westberry v. Gislaved Gummi AB.* 178 F.3d 257, 261 (4th Cir.1999). In analyzing reliability, a court

should consider factors such as:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper, 259 F.3d at 199;*see Daubert,* 509 U.S. at 592–94.

Much of the parties' dispute regarding expert testimony concerns whether each of the various experts is qualified and has a reliable basis to offer testimony as to the alleged causal connection between Aredia and Zometa and ONJ. The court analyzes the arguments seriatim.

As for Dr. Marx, Dr. Marx is a qualified expert and has a reliable basis to offer testimony regarding the efficacy of certain treatments in preventing bisphosphonate-induced ONJ ("BIONJ"), general causation based on adverse event reports, and the biological mechanism by which bisphosphonates may cause BIONJ. To the extent plaintiffs seek to introduce Dr. Marx's opinion on whether Novartis acted in "bad faith," the court agrees with Novartis that Dr. Marx lacks a basis to testify on the subject, and such testimony will be excluded. Likewise, the court will not permit Dr. Marx to criticize Novartis's clinical trials or opine on patients in those trials given his lack of expertise or any reliable methodology.

***4** As for Dr. Parisian, Dr. Parisian is an expert whose testimony may be helpful to a jury regarding the FDA drug-approval process including regulations governing the approval, advertising, and marketing of pharmaceuticals. To the extent she also seeks to opine on whether Novartis complied with the regulations, industry ghostwriting or funding of scientific studies, causation, whether the labels provided adequate warnings in this case, state of mind, or to provide other testimony that would unduly prejudicial, irrelevant, or outside the scope of her expertise, the court will not allow her to do so.

As for Dr. Skubitz, Dr. Skubitz is a qualified expert and has a reliable basis to offer testimony regarding the efficacy of pretreatment dental screening in preventing BIONJ. The court, however, will not permit him to testify about alternative dosing or labeling.

As for Dr. Vogel, Dr. Vogel is a qualified expert and has a reliable basis to offer testimony regarding the efficacy of pretreatment dental screening in preventing BIONJ, the incidence rate of ONJ, the efficacy of reduced dosing schedules, and general causation. The court, however, will not permit him to testify about corporate conduct, labeling, or the biological mechanism by which bisphosphonates may cause BIONJ.

As for Doctors Nance and Blakey, these witnesses are qualified experts and each has a reliable basis to offer testimony regarding specific causation of plaintiff Earp's ONJ. Plaintiffs do not appear to contend that Doctors Yoffe, Kritz, Petrocella, and Davis will testify that Aredia or Zometa specifically caused plaintiff Earp's ONJ, and plaintiffs do not argue that these treating physicians have any basis for so opining. *See* Pls.' Mem. Opp. Mot. Exclude [D.E. 80] 24–25. Accordingly, any such testimony will be excluded. However, Doctors Petrocella and Davis are experts qualified to discuss how bisphosphonate-related ONJ causes difficulty in treatment and how their profession's understanding of Aredia and Zometa and its links to ONJ would have affected their treatment of plaintiff Earp.

In accordance with the foregoing conclusions, the court denies in part Novartis's motions to exclude expert testimony [D.E. 66, 68, 70, 72, 74, 76]. The court notes that many of Novartis's objections go to the weight of the experts' testimony and not to its admissibility. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."*Daubert,* 509 U.S. at 596.The court will further consider as part of the motions in limine or at trial whether the testimony of any expert should be limited as irrelevant, unduly prejudicial, or outside the scope of his or her expertise. The court denies plaintiffs' cross-motion [D.E. 84] regarding the motions to exclude as moot.

III.

Next, the court considers Novartis's motion for summary judgment [D.E. 15, 78]. The court reviews Novartis's motion for summary judgment under the familiar standard of Rule 56. Summary judgment is appropriate when, after reviewing the record taken as a whole, no genuine issue of material fact exists, and the moving party is entitled to judgment as a matter of law.Fed.R.Civ.P. 56(a); *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 24748 (1986). The party seeking summary judgment bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett,* 477 U.S. 317, 325 (1986). Once the moving party has met its burden, the nonmoving party may not rest on the allegations or

denials in its pleading, *Anderson.* 477 U.S. at 248–49, but "must come forward with specific facts showing that there is a genuine issue for trial."*Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986) (emphasis and quotation omitted). A trial court reviewing a motion for summary judgment should determine whether a genuine issue of material fact exists for trial.*Anderson.* 477 U.S. at 249.In making this determination, the court must view the evidence and the inferences drawn therefrom in the light most favorable to plaintiffs. *Scott v. Harris,* 550 U.S. 372, 378 (2007).

***5** Novartis argues that (1) plaintiffs' claims are barred by North Carolina's statute of limitations; (2) plaintiffs have presented no admissible evidence of causation; (3) plaintiffs have failed to show that Novartis failed to provide a timely or adequate warning, or that a different warning would have prevented Earp's jaw injury; (4) plaintiffs fail to provide evidence of any express warranty that Novartis violated; (5) plaintiffs have no evidence that Aredia and Zometa were not fit and effective for their intended purpose; (6) plaintiffs' strict liability, negligent manufacturing, and negligent design claims fail as a matter of law; and (7) Patricia Earp's claim for loss of consortium fails because it is derivative of the other claims. Def.'s Mem. Supp. Mot. Summ. J. [D.E. 79] 12.

North Carolina's statute of limitations for personal injury provides a three-year limitations period that does not "accrue until bodily harm to the claimant ... becomes apparent or ought reasonably to have become apparent to the claimant."N.C. Gen.Stat. § 1–52(16). In the case of diseases, the limitations period does not begin until a medical diagnosis reveals the nature of plaintiff's disease. *See Wilder v. Amatex Corp.,* 314 N.C. 550, 559–61, 336 S.E.2d 66, 71–72 (1985); *cf. Wilson v. McLeod Oil Co.,* 327 N.C. 491, 512, 398 S.E.2d 586, 596–97 (1990); *Black v. Littlejohn,* 312 N.C. 626, 64345, 325 S.E.2d 469, 48082 (1985); *Crawford v. Boyette,* 121 N.C.App. 67, 7072, 464 S.E.2d 301, 304 (1995). Viewing the evidence in the light most favorable to plaintiffs, Earp's jaw condition was not diagnosed as bisphosphonate-related ONJ until October 11, 2005. *E.g.,* Blakey Dep. [D.E. 80–14] 113–14. Therefore, viewing the evidence in the light most favorable to plaintiffs, plaintiffs' September 1, 2006 complaint was timely filed.

Next, Novartis argues that plaintiffs lack evidence of causation. Plaintiffs, however, have proffered sufficient, admissible expert testimony concerning causation to create a genuine issue of fact for trial.

As for the adequacy of the warnings concerning Aredia and Zometa, numerous material factual issues remain, such as what Novartis knew about the risks of bisphosphonates, when it knew or should have known those risks, and whether it adequately conveyed the risks to physicians. Furthermore, viewing the evidence in the light most favorable to plaintiffs, plaintiffs have produced evidence that creates a genuine issue as to whether Earp's treatment would have been different if Novartis had provided adequate warning. *See, e.g .,* Yoffe Dep. [D.E. 80–16] 11920; Davis Dep. [D.E. 80–24] 96; Kritz Dep. [D.E. 80–27] 9092.

As for plaintiffs' claim for breach of express warranty, "[a] claim for breach of express warranty ... requires proof of (1) an express warranty as to a fact or promise relating to the goods, (2) which was relied upon by the plaintiff in making his decision to purchase, (3) and that this express warranty was breached by the defendant."*Harbor Point Homeowners' Ass'n ex rel. Bd. of Dirs. v. DJF Enters., Inc.,* 206 N.C.App. 152, 162, 697 S.E.2d 439, 447 (2010). Plaintiffs have not provided evidence of any express warranty Novartis or its agents made or violated. *See* Pls.' Mem. Opp. Summ. J. [D.E. 81] 2728. Accordingly, the court grants summary judgment to Novartis on this claim.

***6** As for plaintiffs' claim for breach of implied warranty, Novartis argues that plaintiffs' claim "is actually a failure to warn claim under a different name."Def.'s Mem. Supp. Mot. Summ. J. 22. However, "a failure to warn of dangerous propensities concerning a product may create an action of breach of implied warranty of merchantability."*Bryant v. Adams,* 116 N.C.App. 448, 468, 448 S.E.2d 832, 843 (1994); *see Nicholson v. Am. Safety Util. Corp.,* 124 N.C.App. 59, 69, 476 S.E.2d 672, 678 (1996). Viewing the evidence in the light most favorable to plaintiffs, genuine issues of material fact remain concerning this claim. Thus, the court denies summary judgment on this claim.

As for plaintiffs' claims for strict liability and manufacturing defect, plaintiffs "are not pressing" either claim in this case. Pls.' Mem. Opp. Summ. J. 28. Accordingly, the court grants summary judgment to Novartis on these claims.

As for plaintiffs' design defect claim, plaintiffs must prove, among other things, either one of the following:

> (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

(2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

N.C. Gen.Stat. § 99B–6(a); *see DeWitt v. Eveready Battery Co.*, 144 N.C.App. 143, 154–55, 550 S.E.2d 511, 51819 (2001), *aff'd*,355 N.C. 672, 565 S.E.2d 140 (2002). Plaintiffs have not alleged or produced evidence of any safer alternative design that would have prevented or substantially reduced the risk of harm of using Aredia or Zometa. Furthermore, plaintiffs' evidence shows that physicians continue to prescribe and use Aredia and Zometa after becoming aware of the allegedly defective design of the products. *E.g.*, Yoffe Pep. 11819. Thus, plaintiffs have not shown that the formulation of these medications was so unreasonable that a reasonable person would not use or consume them. Accordingly, the court grants summary judgment to Novartis on this claim.

Finally, the parties agree that Patricia Earp's loss of consortium claim rises or falls with plaintiffs' other claims. Accordingly, the court denies summary judgment on this claim.

IV.

In sum, the court DENIES plaintiffs' motion to amend the complaint [D.E. 55], DENIES in part defendant's motions to exclude expert testimony [D.E. 66, 68, 70, 72, 74, 76], DENIES as moot plaintiffs' cross-motion regarding the motion to exclude [D.E. 84], and GRANTS IN PART AND DENIES IN PART defendant's motion for summary judgment [D.E. 78]. The parties shall schedule and complete mediation no later than November 15, 2013.

***7** SO ORDERED.

End of Document

2010 WL 4104707
Only the Westlaw citation is currently available.
United States District Court,
M.D. North Carolina.

Herbert FUSSMAN, individually and as Administrator of the Estate of Rita Fussman, Plaintiff,
v.
NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.

No. 1:06CV149. | Oct. 18, 2010.

West KeySummary

1 **Federal Civil Procedure**

Tort Cases in General

A genuine issue of material fact existed as to whether additional warnings by pharmaceutical manufacturer regarding bisphosphonates to prescribing physician would have been relayed to patient, thereby preventing damage to her health. Physician indicated that it was her practice to provide warning information and potential side effects to her patients. Patient stated that if she had been warned of the potential connection between bisphosphonates and Osteonecrosis of the Jaw, she would have refrained from using the drug.

Cases that cite this headnote

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ORDER AND MEMORANDUM OPINION

JAMES A. BEATY, District Judge.

***1** This matter is presently before the Court on multiple pre-trial motions, including Defendant's Motion for Summary Judgment [Doc. # 47]. These various motions came before the Court during a hearing on various pre-trial matters on September 28, 2010. The present Order and Memorandum Opinion solely addresses Defendant's Motion for Summary Judgment.

I. BACKGROUND

This case involves claims by Herbert Fussman, individually and as the Administrator of the Estate of Rita Fussman, ("Plaintiff") against Novartis Pharmaceuticals Corporation ("Defendant" or "Novartis") related to injuries suffered by Mrs. Fussman allegedly caused by certain of Defendant's prescription medications known as Aredia and Zometa. Mrs. Fussman began taking Aredia in June 2001 while she was being treated for a recurrence of breast cancer. The Aredia was prescribed by Mrs. Fussman's oncologist, Dr. Heather Shaw. In November 2001, Dr. Shaw switched Mrs. Fussman's prescription from Aredia to Zometa. Mrs. Fussman continued on the Zometa until June 2005, with a one-month break in October 2004. Plaintiff contends that bisphosphonates, including Aredia and Zometa, can cause bisphosphonate-related Osteonecrosis of the Jaw ("ONJ"), and that the Aredia and Zometa taken by Mrs. Fussman caused Mrs. Fussman to develop ONJ. During the time that she was taking the Aredia and Zometa, Mrs. Fussman underwent multiple dental procedures and experienced significant dental problems. Plaintiff contends that Defendant failed to adequately warn Mrs. Fussman and her medical providers of the risk of ONJ associated with Aredia and Zometa.

This case was originally filed in this Court but was transferred to the Middle District of Tennessee Multi–District Litigation ("MDL") related to

Aredia/Zometa claims. After discovery concluded in the MDL Court, Defendant filed Motions for Summary Judgment with the MDL Court. In the MDL Summary Judgment motions, Defendant asserted that the warnings it had provided were adequate as a matter of law, but on this issue, the MDL Court specifically found that "there are genuine issues of material fact as to the adequacy of Defendant's warnings."Defendant also alleged that summary judgment should be granted because Plaintiff could not establish proximate causation. On the question of proximate causation, Defendant alleged that Plaintiff had not shown that additional warnings would have made any difference in the behavior of Mrs. Fussman and her physicians or prevented her ONJ. However, on this issue, the MDL Court found that Plaintiff had "offered sufficient proof to show that there are genuine issues of material fact as to whether the alleged failure to warn was a proximate cause of Mrs. Fussman's injuries" because: (1) Mrs. Fussman testified that "knowing what she does now about Aredia and Zometa and her jaw problems, she would not have taken either of those drugs"; and (2) Mrs. Fussman's dentists, Dr. Shroer and Dr. Wagoner, both testified that their treatment for Mrs. Fussman would have been different if they had known about bisphosphonates and ONJ. The MDL Court therefore denied Defendant's Motion for Summary Judgment with respect to Plaintiff's claims for negligent failure to warn and breach of implied warranty based on failure to provide adequate warnings. As a result of this determination, the MDL Court remanded the case back to this Court for trial on Plaintiff's claims for Negligent Design and Negligent Failure to Warn (which were both based on the alleged failure to warn), Breach of Implied Warranty, and Loss of Consortium.

II. PRESENT MOTION FOR SUMMARY JUDGMENT

***2** Following the remand to this Court, the parties took the deposition of Dr. Shaw, Mrs. Fussman's oncologist, who had been unavailable during the MDL proceedings. Based on the deposition of Dr. Shaw, Defendant filed this additional Motion for Summary Judgment alleging that Plaintiff cannot now establish a genuine issue of material fact on the question of proximate causation, specifically contending that Plaintiff cannot establish that the alleged lack of adequate warnings to Dr. Shaw was the proximate cause of Plaintiff's injury.

Under North Carolina law, " '[p]roximate cause is a cause which in natural and continuous sequence, unbroken by any new and independent cause, produced the plaintiff's injuries, and without which the injuries would not have occurred, and one from which a person of ordinary prudence could have reasonably foreseen that such a result, or consequences of a generally injurious nature, was probable under all the facts as they existed.' " *Gaines v. Cumberland County Hospital System, Inc.*, 692 S.E.2d 119, 122 (N.C.Ct.App.2010) (quoting *Hairston v. Alexander Tank & Equipment Co.*, 310 N.C. 227, 233, 311 S.E.2d 559, 565 (1984). North Carolina courts have cautioned that " 'it is only in exceptional cases, in which reasonable minds cannot differ as to foreseeability of injury, that a court should decide proximate cause as a matter of law. Proximate cause is ordinarily a question of fact for the jury, to be solved by the exercise of good common sense in the consideration of the evidence of each particular case' .... [and] '[c]ausation is an inference of fact to be drawn from other facts and circumstances.' " *Id.* (quoting *Williams v. Carolina Power & Light Co.*, 296 N.C. 400, 403, 250 S.E.2d 255, 258 (1979) and *Turner v. Duke University*, 325 N.C. 152, 162, 381 S.E.2d 706, 712 (1989)).

In considering Defendant's present Motion for Summary Judgment, the Court notes that Defendant's Motion is based on two underlying contentions. First, Defendant contends as a legal matter that in a prescription drug case based on negligent failure to warn, North Carolina law requires that proximate cause be established only through the prescribing physician, not other treating physicians or medical professionals. As such, Defendant contends that Dr. Shaw is the only relevant actor in establishing proximate cause. Second, Defendant contends that Plaintiff cannot establish proximate cause through Dr. Shaw because (a) the requisite causal link is broken because Dr. Shaw independently became aware of the alleged connection between bisphosphonates and ONJ, notwithstanding the warnings (or lack of warnings) provided by Defendant; and (b) Plaintiff cannot establish that Dr. Shaw would have acted any differently even if she had been given additional warnings. Each of these contentions will be considered in turn.

First, Defendant contends that proximate cause can be established only through Mrs. Fussman's prescribing physician, Dr. Shaw, and not Plaintiff's other treating physicians or medical professionals. However, no North Carolina state court decision has adopted such a limitation. Instead, the North Carolina Court of Appeals has specifically concluded that proximate cause may be established based on failure to warn not only the prescribing physician, but also other "foreseeable" treating medical professionals pursuant to "standard principles of negligence law." *See Holley v. Burroughs Wellcome Co.*, 74 N.C.App. 736, 746, 330 S.E.2d 228, 235 (1985). In affirming this decision, the North Carolina Supreme Court concluded that proximate cause could be

established based on expert testimony that "the failure of medical personnel to timely recognize and treat [plaintiff's] condition was in part due to defendants' inadequate warnings and overpromotion," thus extending proximate cause to treating medical personnel (not just the prescribing physician), based on information provided by the manufacturer to the medical profession generally through "medical journals, professional literature distributions and package inserts."*See Holley v. Burroughs Wellcome Co.*, 318 N.C. 352, 360–61, 348 S.E.2d 772, 776–77 (1986). Pursuant to this analysis, proximate cause may be established through other health-care providers, not just the prescribing physician.[1] This analysis is consistent with the Restatement of Law (Third), which provides that a drug is defective if adequate warnings are not provided to "prescribing and other health-care providers who are in a position to reduce the risk of harm in accordance with the instructions or warnings."Restatement of Torts (Third) § 6 and comment (c) ("Beyond informing prescribing health-care providers, a drug or device manufacturer may have a duty under the law of negligence to use reasonable measures to supply instructions or warnings to nonprescribing health-care providers who are in positions to act on such information so as to reduce or prevent injury to patients.").[2]

***3** Defendant nevertheless contends that this rule as set out in *Holley* has been supplanted by the relevant provisions of the North Carolina Products Liability Law, N.C. Gen.Stat. § 99B5. Under Section 99B–5(a), to establish a claim for product liability against a manufacturer based on inadequate warnings, a claimant must prove (1) that the manufacturer acted unreasonably in failing to provide adequate warning or instruction; (2) that the failure to provide adequate warning or instruction was the proximate cause of the harm for which damages are sought; and (3) that the manufacturer either (a) knew or should have known at the time the product left the manufacturer's control that the product, without an adequate warning, created an unreasonably dangerous condition that posed a substantial risk of harm to a reasonably foreseeable claimant, or (b) became aware or in the exercise of ordinary care should have known after the product left the manufacturer's control that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and "failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances."*See*N.C. Gen.Stat. § 99B–5(a). In addition, the Court notes that even if the claimant can establish all of the elements of his claim, Section 99B–5(c) goes further to create an affirmative defense for manufacturers and sellers of prescription drugs. Specifically, § 99B–5(c) provides that "[n]otwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product."Under this "safe harbor," a prescription drug manufacturer is not liable for alleged failure to warn a consumer directly if (1) the manufacturer provided an adequate warning to the prescribing physician; and if (2) the FDA does not require direct consumer warnings for the product. Thus, the adequacy of the warning provided to the prescribing physician is the key concern in establishing this defense. This concern is demonstrated within the North Carolina Pattern Jury Instructions, whereby this "safe harbor" is presented to the jury as an affirmative defense on which the defendant bears the burden of proof, requiring the defendant to prove that it provided an adequate warning or instruction to the prescribing physician who prescribed the drug to the plaintiff. In the present case, the MDL Court has already determined that there are genuine issues of material fact regarding the adequacy of the warnings provided by Defendant. As such, it would be appropriate to present this defense to the jury for determination in this case. However, the Court will not extend this defense beyond the statutory language. Therefore, to the extent that Defendant contends that as a legal matter, § 99B–5(c) provides more than an affirmative defense or otherwise alters the proximate cause analysis in this case, the Court rejects that contention.

***4** Moreover, even if the Court accepted Defendant's legal contentions in this regard and limited the proximate cause analysis to only Dr. Shaw, the Court would still find that there are genuine issues of material fact related to Dr. Shaw. As noted above, Defendant contends that Plaintiff cannot establish proximate cause through Dr. Shaw because (a) the requisite causal link is broken because Dr. Shaw independently became aware of the alleged connection between bisphosphonates and ONJ, notwithstanding the warnings (or lack of warnings) provided by Defendant; and (b) Defendant further contends that Plaintiff cannot establish that Dr. Shaw would have acted any differently even if she had been given additional warnings. On the first point, that is, the "independent knowledge" contention, Defendant contends that Dr. Shaw independently became aware of a case report regarding a potential association between bisphosphonates and ONJ, and therefore no additional warnings from Defendant were required. However, it

appears that based on the deposition testimony, Dr. Shaw does not recall exactly what she knew about bisphosphonates and ONJ or when she learned of the potential association, and she may even now be unaware of the risks and connection alleged by Plaintiff between bisphosphonates and ONJ. As a result, there are genuine issues regarding what Dr. Shaw independently knew about bisphosphonates and ONJ. In addition, the Court notes that Defendant's allegation that Dr. Shaw had "independent knowledge" of the alleged risks would not necessarily support summary judgment on this claim. *See Holley,* 318 N.C. at 357–60, 348 S.E.2d at 775–77 (holding that even where the prescribing physician stated that he was independently aware of the risks, there were still genuine issues of fact precluding summary judgment on proximate cause, because the physician relied in part on the medical literature, which was potentially affected by the package inserts and promotional information from the drug manufacturer). Therefore, the alleged "independent knowledge" of Dr. Shaw would not warrant summary judgment in this case.

With respect to whether Dr. Shaw would have acted any differently even if she had been given additional warnings, Defendant contends that Dr. Shaw stated during her deposition that she would have continued to recommend the Aredia and Zometa to Mrs. Fussman even if Defendant had provided additional warnings. However, Dr. Shaw also indicated that she would have provided other advice to Mrs. Fussman prior to Mrs. Fussman's dental procedures, although she said it was "hard to say" exactly how the advice would have differed because the connection with ONJ"wasn't even on her radar screen."It also appears that Dr. Shaw did in fact change her treatment advice for other patients receiving bisphosphonates after receiving a "Dear Doctor" letter from Defendant regarding the need for dental screenings. Therefore, there is a genuine issue with respect to whether Dr. Shaw would have provided different treatment advice to Mrs. Fussman had the additional warnings been provided.

***5** Finally, the Court notes that Dr. Shaw also testified that her practice was to discuss risks and potential adverse events with her patients, and Mrs. Fussman testified that she would not have taken the drug if she had been warned of the potential connection between bisphosphonates and ONJ. In these circumstances, there is a genuine issue with respect to whether additional warnings from Defendant would have been provided by Dr. Shaw to Mrs. Fussman, who claims that she would have then refused the drug. Thus, unlike cases where the prescribing physician testifies that he or she would have prescribed the drug without advising the patient of the risks or providing the warnings to the patient, *e.g., Stanback v. Parke, Davis & Co.,* 657 F.2d 642, 645 (4th Cir.1981), in the present case, the prescribing physician, Dr. Shaw, indicated that it was her practice to provide the warning information and potential side effects to her patients. As noted above, Mrs. Fussman testified that she would have ceased the bisphosphonate treatment had she been warned of the potential side effects. *Cf. Stanback,* 657 F.2d at 645–46 (finding no evidence of causation where the prescribing physician's "decisions and actions would not have been affected in the least by the communication of an adequate warning" but noting that "in a failure to warn case when the evidence suggests that a physician might have heeded an adequate warning ... it is clear that the failure to warn could make a difference and would be a cause in fact of an injury"). For all of these reasons, and having considered the evidence presented, the Court concludes that there are genuine issues of material fact precluding summary judgment in this case.

III. CONCLUSION

Therefore, having considered Defendant's Motion for Summary Judgment, the Court declines to adopt Defendant's legal contention that proximate cause must be established only through the prescribing physician. Moreover, even if the Court accepted that legal contention, the Court would still conclude that there are genuine issues of material fact regarding whether proximate cause could be established through Dr. Shaw. Given that the MDL Court has already determined that this case should be resolved by a jury, the Court finds that there is nothing in Dr. Shaw's deposition that would change that result at this stage of the matter.

IT IS THEREFORE ORDERED that Defendant's Motion for Summary Judgment [Doc. # 47] be DENIED.

Footnotes

1 In this regard, the Court notes that the MDL Court has already determined that under North Carolina law, Plaintiff has "offered sufficient proof to show that there are genuine issues of material fact as to whether the alleged failure to warn was a proximate cause of Mrs. Fussman's injuries" because Mrs. Fussman's other health care providers, particularly Dr. Shroer and Dr. Wagoner, testified that their treatment for Mrs. Fussman would have been different if they had known about bisphosphonates and ONJ. The

Court will not revisit that determination.

2 The Court notes that the analysis set out in *Holley* would apply in cases where other medical personnel, beyond just the prescribing physician, were in a position to recognize the plaintiff's adverse reaction to the drug and take steps that would have reduced her risk of injury. *See Holley,* 318 N.C. at 360–61, 348 S.E.2d at 776–77;*see also Stanback v. Parke, Davis & Co.,* 657 F.2d 642, 645 n. 4 (4th Cir.1981) ("In certain failure to warn cases ... it is possible to establish evidence of causation ... by showing that a properly warned physician could have detected early signs of an adverse reaction to a drug and reduced the injury."). The present case raises such claims because Plaintiff contends, *inter alia,* that other medical personnel, including Dr. Schroer and Dr. Wagoner, could have taken steps to reduce her risk of injury, but did not because of the inadequate warnings provided by Defendant in the package inserts, promotional material, and medical literature. In contrast, Defendant contends that the causation determination must be limited to the prescribing physician's initial prescribing decision, citing *Stanback,* 657 F.2d at 645. However, the Fourth Circuit in *Stanback,* applying Virginia law, specifically noted that such a limitation was only appropriate in that case because "there is no specific treatment the physician can use to stop" the adverse reaction to the drug. *See Stanback,* 657 F.2d at 645 n. 4. Thus, such a limitation would not apply if the adverse reaction can be treated or the risk of injury subsequently reduced, as Plaintiff contends in the present case.

2013 WL 1623609
Only the Westlaw citation is currently available.
United States District Court, W.D. North Carolina, Asheville Division.

Lloyd Steven KISER, Plaintiff,
v.
TRACTOR SUPPLY COMPANY, a Delaware Corporation, and "John Doe," a person or business whose identification is unknown to Plaintiff at this time, Defendants.

Civil No. 1:12–cv–00042–MR–DLH. | April 15, 2013.

Attorneys and Law Firms

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MEMORANDUM OF DECISION AND ORDER

MARTIN REIDINGER, District Judge.

***1 THIS MATTER** is before the Court on the Defendant's Motion for Summary Judgment [Doc. 16].

I. PROCEDURAL BACKGROUND

The Plaintiff Lloyd Steven Kiser initiated this products liability action on January 27, 2012, in the Cleveland County General Court of Justice, Superior Court Division, against the seller of the allegedly defective product, Tractor Supply Company ("Tractor Supply"), and the manufacturer of the allegedly defective product, identified in the Complaint only as "John Doe." [Complaint, Doc. 1–1 at 3]. On March 3, 2012, Tractor Supply removed the action to this Court on the basis of diversity jurisdiction. [Notice of Removal, Doc. 1]. Tractor Supply filed its Answer on March 8, 2012. [Doc. 3].

On October 15, 2012, the Plaintiff filed a Motion to Amend his Complaint in order to substitute Behrens Manufacturing LLC as the "John Doe" Defendant. On October 17, 2012, Magistrate Judge Howell granted the Plaintiff's Motion and gave him until October 24, 2012 to file an Amended Complaint. [Doc. 14]. The Plaintiff, however, did not file an Amended Complaint within the time required.

On December 31, 2012, in keeping with the deadlines set forth in the Pretrial Order and Case Management Plan [Doc. 6], Tractor Supply filed its Motion for Summary Judgment. [Doc. 16]. Thereafter, on January 3, 2013, the Plaintiff filed an Amended Complaint. [Doc. 18]. Tractor Supply immediately moved to strike the Amended Complaint. [Doc. 19]. On January 16, 2013, Judge Howell granted that motion. [Doc. 22]. The Plaintiff moved for reconsideration of Judge Howell's Order, which was denied. [Docs. 23, 24]. The Plaintiff never filed a response to Tractor Supply's Motion for Summary Judgment.

II. THE SUMMARY JUDGMENT STANDARD

Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."Fed.R.Civ.P. 56(a). A fact is "material" if it "might affect the outcome of the case."*News and Observer Pub. Co. v. Raleigh–Durham Airport Auth.*, 597 F.3d 570, 576 (4th Cir.2010). A "genuine dispute" exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."*Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

A party asserting that a fact cannot be genuinely disputed must support its assertion with citations to the record. Fed.R.Civ.P. 56(c)(1)."Regardless of whether he may ultimately be responsible for proof and persuasion, the party seeking summary judgment bears an initial burden of demonstrating the absence of a genuine issue of material fact."*Bouchat v. Baltimore Ravens Football Club, Inc.*, 346 F.3d 514, 522 (4th Cir.2003). If this showing is made, the burden then shifts to the non-moving party who must convince the Court that a triable issue does exist. *Id.*

In considering the facts for the purposes of a summary judgment motion, the Court must view the pleadings and materials presented in the light most favorable to the nonmoving party and must draw all reasonable inferences in the nonmoving party's favor. *Adams v. Trustees of the Univ. of N.C.-Wilmington*, 640 F.3d 550, 556 (4th

Cir.2011). Where the nonmoving party has not responded to the motion, however, the Court may consider the forecast of evidence presented by the movant to be undisputed for the purposes of the present motion. *See*Fed.R.Civ.P. 56(e)(2).

III. FACTUAL BACKGROUND

***2** In light of the Plaintiff's failure to respond to the Defendant's Motion, the following forecast of evidence is not in dispute.

At some point in early January 2009, the Plaintiff purchased a galvanized metal bucket from Tractor Supply. [Complaint, Doc. 1–1 at ¶ 4]. On or about January 29, 2009, the Plaintiff was using the bucket to transport (or "pull") hot grease from a stove while working at a restaurant called the Shelby Fish Camp. [*Id.* at ¶ 5]. The Plaintiff estimated the temperature of the grease to be either 325 or 375 degrees. [*See* Complaint, Doc. 1–1 at ¶ 4; Deposition of Lloyd Kiser ("Pl.Dep."), Doc. 16–1 at 44]. As he was transporting the grease, the bottom of the bucket collapsed causing the grease to fall onto the Plaintiff's lower legs and injure him. [Complaint, Doc. 1–1 at ¶ 5].

Plaintiff testified that these buckets were periodically purchased from Tractor Supply for the restaurant every three or four months. [Pl. Dep., Doc. 16–1 at 34]. Plaintiff admitted that when he purchased buckets from the Defendant, he only sought a metal bucket, and not a particular brand. [*Id.* at 36]. Plaintiff further admitted that he was aware these buckets would begin to fail and "seep" grease out of the bottom of the bucket and onto the floor after a few months of use, at which point the restaurant would discard the old bucket and purchase a new one. [*Id.* at 35].

While the Plaintiff alleges in his verified Complaint that he purchased the bucket at issue in this case [Complaint, Doc. 1–1 at ¶ 4], the Plaintiff testified in his deposition that he was not sure whether he or his brother, Scott Eugene Kiser, purchased it. [*Id.* at 40]. The Plaintiff testified that both he and his brother purchased a bucket from Tractor Supply around the same time period. [*Id.*].

The Plaintiff could not recall whether he discussed these buckets with Tractor Supply employees when he purchased them. [*Id.* at 43]. Further, while the Plaintiff claims that unknown and unidentified employees of Tractor Supply knew that the buckets were being used at the restaurant, he could not recall whether he ever told these employees that he was using the buckets for "pulling" or transferring the hot grease. [*Id.* at 43–44].

When the Plaintiff purchased a bucket (which may or may not have been the bucket at issue) from Tractor Supply a few weeks prior to his accident, he examined it and did not see any problems or defects. [*Id.* at 53–54].

Plaintiff does not know why the bucket collapsed. [*Id.* at 57]. Plaintiff is further unaware of any government or industry standards that were violated by the Defendant regarding the sale of the bucket. [Plaintiff's Response to Interrogatory No. 4, Doc. 16–5 at 2–3]. Even after the Plaintiff was injured by the alleged failure of the bucket, he continued to purchase the same type of buckets from Tractor Supply for transporting hot grease from the restaurant's stoves. [Pl. Dep., Doc. 16–1 at 77].

***3** The Plaintiff's brother, Scott Kiser, testified that when he purchased his bucket from Tractor Supply a few weeks before the Plaintiff's incident, he inspected it by holding it up to the light and noted that "everything looked great." [Deposition of Scott Kiser ("S. Kiser Dep."), Doc. 16–2 at 24]. Scott Kiser also confirmed that no Tractor Supply employees ever made representations to him about the buckets that he purchased from the store. [*Id.* at 19]. While Scott Kiser testified that one Tractor Supply employee named Kim Hamrick generally "knew" that he purchased these buckets to clean the restaurant's stoves, he admitted that he never told her *how* the bucket was used to clean the stove, or that 375 degree grease was being placed in the bucket for transport. [*Id.* at 19–20]. More importantly, Scott Kiser admitted that after being told that the bucket would be used to "clean the stove," Kim Hamrick did not make any representations about the adequacy of the bucket for that purpose. [*Id.*]. Lastly, Scott Kiser admitted that at the time of this specific bucket purchase three weeks prior to the Plaintiff's incident, he did not have any such conversations with Kim Hamrick. [*Id.* at 20].

Like the Plaintiff, Scott Kiser also testified that the hot grease would start to "seep" out of the bottom of the buckets they purchased from Tractor Supply after less than three months of use. [*Id.* at 14]. Even after his brother's incident, Scott Kiser continued to purchase these same buckets from Tractor Supply for transporting hot grease. [*Id.* at 26].

IV. DISCUSSION

A. Tractor Supply's Motion for Summary Judgment

At the outset, the Court notes that the specific causes of action asserted by the Plaintiff against Tractor Supply are not entirely clear. It appears, however, that the Plaintiff

has alleged claims of breach of implied warranty (for both merchantability and fitness for a particular purpose), breach of express warranty, and product liability/negligence pursuant to N.C. Gen.Stat. § 99B. For the reasons that follow, the Court concludes that Tractor Supply is entitled to summary judgment on each of these claims.

1. Plaintiff's Claims for Implied Warranty of Merchantability and Negligence/Product Liability

In order to bring a products liability claim based either on negligence or a breach of implied warranty of merchantability, a plaintiff must prove that the product was defective when it left the defendant's control. *See DeWitt v. Eveready Battery Co.,* 355 N.C. 672, 683, 565 S.E.2d 140, 147 (2002) ("To establish a breach of implied warranty of merchantability under the statute, a plaintiff must prove the following elements: (1) that the goods bought and sold were subject to an implied warranty of merchantability; (2) that the goods did not comply with the warranty in that the goods were defective at the time of sale; (3) that his injury was due to the defective nature of the goods; and (4) that damages were suffered as a result.") (internal quotation marks omitted); *Red Hill Hosiery Mill, Inc. v. MagneTek, Inc.,* 138 N.C.App. 70, 75, 530 S.E.2d 321, 326,*disc. rev. denied,*353 N.C. 268, 546 S.E.2d 112 (2000) ("A products liability claim grounded in negligence requires the plaintiff prove (1) the product was defective at the time it left the control of the defendant, (2) the defect was the result of defendant's negligence, and (3) the defect proximately caused plaintiff damage.") (footnote omitted).

***4** In the present case, the Plaintiff has not identified any specific defect in the bucket at issue. The Plaintiff himself testified that he does not know why the bucket failed. He has not identified any obvious defect with the product, nor has he produced any expert witness to identify any latent defect therein. Thus, the Plaintiff has presented no forecast of evidence tending to show that the bucket was defective when it left the control of Tractor Supply. Even assuming that the forecast of evidence could support a finding of a defect, there is no forecast of evidence before the Court to show that the bucket was sold under circumstances in which Tractor Supply had an opportunity to inspect the bucket in a manner that would have revealed, or should have revealed, the manner in which the bucket was allegedly defective. *See*N.C. Gen.Stat. § 99B–2 ("No product liability action, except an action for breach of express warranty, shall be commenced or maintained against any seller ... when the product was acquired and sold by the seller under circumstances in which the seller was afforded no reasonable opportunity to inspect the product in such a manner that would have or should have, in the exercise of reasonable care, revealed the existence of the condition complained of...."). Accordingly, the Plaintiff's product liability claims based on a breach of implied warranty of merchantability and negligence are dismissed.

2. Plaintiff's Claim for Breach of Implied Warranty of Fitness for Particular Purpose

In order to bring a products liability claim based on a breach of the implied warranty of fitness for a particular purpose, a plaintiff must show that "the seller at the time of contracting ha[d] reason to know [of] any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods[.]"N.C. Gen.Stat. § 25–2–315. Here, the undisputed forecast of evidence establishes that Tractor Supply had no reason to know that the Plaintiff and his brother were using the metal buckets to transport hot grease. At most, one Tractor Supply employee was informed that the buckets were being used to clean out the stoves at the restaurant. It is undisputed, however, that neither the Plaintiff nor his brother ever advised anyone at Tractor Supply as to how the buckets were being used in the cleaning process. Further, there is no forecast of evidence that the Plaintiff or his brother relied on the skill of judgment of any Tractor Supply employees in selecting the bucket at issue. Accordingly, the Plaintiff's products liability claim based on a breach of the implied warranty of fitness for a particular purpose is hereby dismissed.

3. Plaintiff's Express Warranty Claim

To establish an express warranty by a seller, a plaintiff must show either: 1) that there was an affirmation of fact or promise made by the seller to the buyer relating to the goods which becomes part of the basis of the bargain; 2) that a description of the goods was given which is made part as part of the basis of the bargain; or 3) that a sample or model was given which is part of the basis of the bargain. *See*N.C. Gen.Stat. § 25–2–313.

***5** In the present case, the Plaintiff has not presented any forecast of evidence that any of those three factual scenarios occurred with the purchase of the bucket from Tractor Supply. When asked whether he ever discussed the buckets with Tractor Supply employees when he purchased them, the Plaintiff testified, "Maybe. I don't know." [Pl. Dep., Doc. 16–1 at 43]. Similarly, Scott Kiser confirmed that no one from Tractor Supply ever said anything about the buckets when he purchased them. There has been no forecast of evidence presented to

establish that any representations were made by Tractor Supply employees when the subject bucket was purchased, or that any sample or model was given as a basis of the bargain. Accordingly, there is no forecast of evidence in the record to support the Plaintiff's express warranty claim against Tractor Supply, and it will therefore be dismissed.

4. Plaintiff's Claim for Inadequate Warning

A retail seller's duty to warn, with respect to products manufactured by another, arises only when two circumstances simultaneously exist: 1) the seller "has actual or constructive knowledge of a particular threatening characteristic of the product" and 2) the seller "has reason to know that the purchaser will not realize the product's menacing propensities for himself."*Ziglar v. E.I. DuPont De Nemours and Co.*, 53 N.C.App. 147, 151, 280 S.E.2d 510, 513 (1981).

Neither circumstance is present in this case. There has been no forecast of evidence to show that Tractor Supply knew or should have known of a dangerous characteristic with the bucket (nor any evidence that a dangerous characteristic even existed). Additionally, there is no forecast of evidence that Tractor Supply had any reason to know that either the Plaintiff, or Scott Kiser, would fail to realize the dangers in using the bucket to transport hot grease. By contrast, the Plaintiff's knowledge that the every bucket eventually "seeped" and leaked at some point suggests that the Plaintiff actually *did* know of that danger. The Plaintiff's claim for inadequate warning is therefore dismissed.

5. Plaintiff's Claim for Inadequate Design or Manufacture

To the extent that the Complaint could be construed as asserting claims against Tractor Supply for inadequate design or formulation of the subject bucket, that claim is subject to summary dismissal simply because there is no forecast of evidence to show that Tractor Supply manufactured or designed the bucket at issue. Without any evidence that Tractor Supply played a role in the design or manufacture of the subject bucket, no claim for negligent design or manufacture can be made against it. *See*N.C. Gen.Stat. § 99B–6 (referencing claims based on inadequate design or formulation against the *manufacturer* of the product). Accordingly, any claims for inadequate design or manufacture asserted against Tractor Supply are hereby dismissed.

B. Dismissal of "John Doe" Defendant

***6** The Plaintiff did not identify and serve the Defendant "John Doe" within 120 days after filing his Complaint as required by Rule 4(m) of the Federal Rules of Civil Procedure, nor has he sought additional time to serve this unnamed Defendant. Accordingly, the Defendant "John Doe" is hereby dismissed from this action without prejudice.

V. ORDER

Accordingly, **IT IS, THEREFORE, ORDERED** that the Defendant Tractor Supply Company's Motion for Summary Judgment [Doc. 16] is **GRANTED,** and all of the Plaintiff's claims against this Defendant are hereby **DISMISSED WITH PREJUDICE.**

IT IS FURTHER ORDERED that the Defendant "John Doe" is hereby **DISMISSED WITHOUT PREJUDICE.**

A Judgment shall be entered simultaneously herewith.

IT IS SO ORDERED.

JUDGMENT

FOR THE REASONS set forth in the Memorandum of Decision and Order entered simultaneously herewith, **IT IS, THEREFORE, ORDERED, ADJUDGED, AND DECREED** that the Defendant Tractor Supply Company's Motion for Summary Judgment is **GRANTED,** and all of the Plaintiff's claims against this Defendant are hereby **DISMISSED WITH PREJUDICE.**The Defendant "John Doe" is hereby **DISMISSED WITHOUT PREJUDICE.**

Parallel Citations

Prod.Liab.Rep. (CCH) P 19,083

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1999 WL 1061973
Only the Westlaw citation is currently available.
United States District Court, M.D. North Carolina.

Jeannie K. LESTER Plaintiff,
v.
DANEK MEDICAL, INC., Sofamor Danek Group, Inc. and Warsaw Orthopedic, Inc. Defendants.

No. 2:96CV1006. | April 16, 1999.

MEMORANDUM OPINION

OSTEEN, J.

***1** This matter comes before the court on Defendants' Motion for Summary Judgment on Plaintiff's causes of actions.

For the reasons discussed herein, the court will grant Defendants' Motion For Summary Judgment.

I. FACTUAL AND PROCEDURAL BACKGROUND

On April 14, 1994, Plaintiff Jeannie K. Lester filed a products liability action against Defendants Danek Medical, Inc., Sofamor Danek Group, Inc., and Warsaw Orthopedic, Inc., alleging that she was injured by Defendants' internal fixation device which was implanted during spinal fusion surgery. (Mem. Supp. Defs.' Mot. Summ. J. at 1 & 3.) [1] Defendants filed a timely answer and raised numerous affirmative defenses. (Answer Am. Compl.)

By order dated February 17, 1998, this case was remanded to this court from MDL Number 1014 proceedings held before Judge Louis Bechtle in Philadelphia. (Mem. Supp. Defs.' Mot. Summ. J. at 3.) All necessary discovery has been concluded. *Id.* at 4. Plaintiff was given 20 days from remand to this court to designate any and all experts. *Id.* To date, Plaintiff has failed to designate any case specific experts. *Id.*

On June 24, 1998, Defendants moved for summary judgment against Plaintiff on all five causes of action. This is the matter now pending before the court. [2]

II. DISCUSSION

Pursuant to Fed.R.Civ.P. 56(c) summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. It is well settled that a genuine issue of fact exists if a reasonable jury, having considered all the evidence, could return a verdict in favor of the non-moving party. *Shaw v. Stroud,* 13 F.3d 791, 798 (4th Cir.1994).

In the present case, Defendants bear the initial burden of showing a lack of evidence to support Plaintiff's cause of action. *Id.* at 798.Assuming this showing is satisfied, the burden then shifts to the non-moving party to convince the court that a genuine issue of fact does exist. For purposes of summary judgment, courts will review the pleadings in the light most favorable to the non-moving party. Plaintiff, however, must still introduce more than a "mere scintilla of evidence" in order to defeat Defendants' motion. *Id.* Furthermore, it is well recognized that if the party opposing the motion fails to establish an essential element of her case, summary judgment is proper. *SeeCelotex Corp. v. Catrett,* 477 U.S. 317, 322–23, 106 S.Ct. 2548, 2552 (1986).

Plaintiff alleges five causes of action arising out of the implantation of Defendants' bone screw device which include a claim for negligence, breach of express warranty, breach of implied warranty, negligent infliction of emotional distress, and fraud. For the reasons stated herein, Defendants' motion for summary judgment on all five counts shall be granted.

A. Plaintiff's Response To Defendants' Motion For Summary Judgment fails to establish any genuine issue of material fact.

***2** It is well settled that "[c]ourts take a liberal policy towards the pleadings of pro se litigants."*Jacobi v. Blocker,* 153 F.R.D. 84, 86 (E.D.Va.1994); *see alsoHaines v. Kerner,* 404 U.S. 519, 520, 92 S.Ct. 594, 596 (1972) (Pro se pleadings are to be held "to less stringent standards than formal pleadings drafted by lawyers."). Viewing the pleadings in the light most favorable to Plaintiff and giving Plaintiff every benefit of the doubt, Plaintiff's pleadings fail to raise any genuine issue of fact which would preclude Defendants' motion for summary judgment. *See* Pl.'s Resp. Defs.' Br. Supp. Mot. Summ. J. (Letter dated Dec. 4, 1998.)

In response to Defendants' motion for summary judgment, Plaintiff maintains:

> I thought that when Bill Horsley withdrew from my case that this was

> over. I don't understand it, I have no funds to pay an attorney, I still need back surgery and unable (sic) to do any gainful work. I cannot pay anybody to do this—all I know is I need more surgery to fix my problem.

Id. (letter dated Dec. 4, 1998 at 1–2.)

Despite the fact that Plaintiff was advised by two letters from this court that failure to reply and/or submit memoranda raising triable issues of fact could lead to dismissal of her case, Plaintiff did not submit any affidavits, expert witness reports, or any evidence which would foreclose the grant of summary judgment. Plaintiff has made only conclusory allegations that she "need(s) more surgery to fix [her] problem."*Id.* at 2. Moreover, Plaintiff has not introduced any evidence which establishes that Defendants' device was defective nor has Plaintiff raised a genuine issue as to the cause of her injuries.

1. Plaintiff has not introduced any evidence establishing that Defendants caused the alleged injuries.

An essential ingredient of all Plaintiff's five causes of action is actual injury caused by Defendants. *See* Defs.' Br. Supp. Mot. Summ. J., Ex. 8—*King v. Danek Med., Inc.,* No. 1:96CV300, Memorandum and Order at 11 (W.D.N.C., Thornburg, J., May 5, 1998) (Granting summary judgment under North Carolina law on Plaintiff's claims of negligence, breach of express warranties, and fraud in the bone screw context where Plaintiff failed to establish that Defendants caused the injuries.). The case law makes it clear that in a products liability action, Plaintiff must establish the following elements:

> (1) evidence of a standard of care owed by the reasonably prudent person in similar circumstances; (2) breach of that standard of care; (3) injury caused directly or proximately by the breach; and (4) loss because of the injury. In addition, a plaintiff must present evidence [that] the product was in a defective condition at the time it left the defendant's control.

See Second Addendum Defs.' Br. Supp. Mot. Summ. J. —*Jimmy R. Kirkman, and wife, Linda R. Kirkman v. Sofamor, S.N.C. and Sofamor Danek Group, Inc.,* No. 1:98CV100, Memorandum and Order at 6 (W.D.N .C., Thornburg, J., July 21, 1998) (citations omitted).

***3** Failure to establish one of the above elements or, at a minimum, raise a triable issue of fact as to any element, is fatal to Plaintiff's claim and cannot defeat a motion for summary judgment. *See*Celotex, 477 U.S. at 322, 106 S.Ct. at 2552 ("[T]he plain language of Rule 56(c) mandates the entry of summary judgment ... against a party who fails to ... establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."); *see also*Anderson v. Radisson Hotel Corp., 834 F.Supp. 1364, 1367 (S.D.Ga.1993) ("[T]he moving party may carry its burden at summary judgment ... by presenting evidence negating an essential element of the non-moving party's claim."). Thus, Defendants have satisfied their initial burden of showing that Plaintiff cannot as a matter of law establish an element which is essential to all of her five causes of action.

Furthermore, North Carolina "courts have long held the cause of back injuries can only be established by expert medical testimony."*Cherry v. Harrell,* 84 N.C.App. 598, 601, 353 S.E.2d 433, 435,*disc. rev. denied,*320 N.C. 167, 358 S.E.2d 49 (1987) (citations omitted); *see also* First Addendum Defs.' Br. Supp. Mot. Summ. J.—*Diana L. Fender v. Sofamor, S.N.C. and Sofamor Danek Group. Inc.,* No. 1:98CV100, Memorandum and Order at 8 (W.D.N.C., Thornburg, J., July 21, 1998) (Summary judgment granted where "Plaintiff has failed to present adequate expert medical evidence that a defect in the medical device manufactured by these Defendants was a proximate cause of Plaintiff's injury or pain."); Mem. Supp. Defs.' Mot. Summ. J., Ex. 8—*King,* slip op. at 7–10 (May 5, 1998). [3]

It is undisputed that the deadline for designating expert witnesses has long passed. (Mem. Supp. Defs.' Mot. Summ. J. at 8.) Furthermore, Plaintiff has not designated a single expert to testify on her behalf as to the cause of her alleged injuries. In the absence of expert testimony establishing causation, Plaintiff has failed to satisfy her burden of establishing at a minimum that a triable issue of fact exists as to causation. [4] Therefore, Defendants are entitled to summary judgment on all of Plaintiff's causes of action. *See* Mem. Supp. Defs.' Mot. Summ. J., Ex. 8—*King,* slip op. at 8 (May 5, 1998) (Summary Judgment granted where "Plaintiffs ha[d] not presented any expert medical evidence that a proximate cause of [the] injury and pain [was] the use of the medical device manufactured by these Defendants."); *see alsoid.,* Ex.

18—*Pride* Order at 1 (Sept.1994). (Granting Defendants' motion for summary judgment and dismissing all claims against Defendants with prejudice "for Plaintiffs' failure to provide expert [witness] reports.").

2. Plaintiff has failed to introduce any evidence of a defective product.

Assuming arguendo that Plaintiff could establish causation, Defendants are nevertheless entitled to summary judgment since Plaintiff has failed to establish the existence of a defective product. Pursuant to North Carolina law, in personal injury cases against a manufacturer of a device, Plaintiff must introduce evidence establishing the existence of a defective condition, regardless of the theory of liability being asserted. *See*Penland v. BIC Corp., 796 F.Supp. 877, 883–84 (W.D.N.C.1992). Moreover, other courts have granted summary judgment in favor of bone screw manufacturers, including Danek, where there was no evidence of a defective product. *See* Mem. Supp. Defs.' Mot. Summ. J., Ex. 8—*King,* slip op. at 7–9.

***4** Plaintiff has failed to introduce any evidence tending to establish the existence of a defective product. To the contrary, Plaintiff's medical records clearly indicate that her instrumentation was not defective. According to Dr. Grobler, Plaintiff's surgeon, after her back surgery in February 1995, "her instrumentation was shown to be stable, well placed on the x-rays that were taken."(Mem. Supp. Defs.' Mot. Summ. J., Ex. 3—Grobler Dep. at 37.) Plaintiff's records also indicate that two months after the surgery her instrumentation remained "intact and there was good alignment."(Mem. Supp. Defs.' Mot. Summ. J., Ex. 2—Grubb Dep. at 17.)

Perhaps the most persuasive evidence for the court is Plaintiff's concession that the instrumentation inserted in her back did not bend, loosen, fracture, migrate, corrode, or fracture or breach the walls of the pedicle. (Mem. Supp. Defs.' Mot. Summ. J., Ex. 4–copy of Compl. dated May 30, 1995, ¶ 4.11(e).) Finally Dr. Grubb, Plaintiff's physician, testified that "the improvement in her deformity was related to the instrumentation"[5] and that "the use of bone screws and pedicles in lumbar surgery is not only the standard of care but the present state of [the] art of lumbar fusion, and is something that can and should be used by appropriately-trained orthopedic surgeons."(Mem. Supp. Defs.' Mot. Summ. J., Ex. 2—Grubb Dep. at 13.)[6]

Moreover, Plaintiff cannot claim that the lack of FDA approval of the TSRH system for use in the vertebral pedicles constitutes a defect. A widely accepted and legal practice in the medical community is "off label use," where a doctor puts a device to use not contained on the FDA-cleared label. *See* First Addendum Defs.' Br. Supp. Mot. Summ. J.—*Fender,* slip op. at (Holding that since off label use by a physician is not prohibited by the FDA, lack of FDA approval does not render the device defective.); *see also* Mem. Supp. Defs.' Mot. Summ. J., Ex. 13—*Scott v. Cedars–Sinai Med. Ctr.,* No. BC 132064, slip op. at 5 (Cal.Super., Los Angeles County Oct. 20, 1997); *Washington Legal Found. v. Kessler,* 880 F.Supp. 26, 28 n. 1 (D.D.C.1995) ("[I]t is not unlawful for doctors to employ or prescribe medical products for 'unapproved' uses.").

In the present action, regardless of whether the FDA approved the TSRH system for use in the vertebral pedicles at the time of Plaintiff's surgery, Dr. Grobler was legally entitled to put the instrumentation to that use. Therefore, the status of the instrumentation by the FDA cannot constitute a defective product.

B. Defendants motion for summary judgment should be granted on Plaintiff's failure to warn claim.

Defendants contend that Plaintiff's claims based on an alleged failure to warn[7] fails as a matter of law under the Learned Intermediary Doctrine. Because Plaintiff has failed to introduce any evidence tending to establish the cause of Plaintiff's injuries, the court need not address the Learned Intermediary Doctrine and its effect on Plaintiff's cause of action. *See* Fourth Addendum Defs.' Br. Supp. Mot. Summ. J.—*Geneva T. Hill and husband. Gaston N. Hill v. Sofamor, S.N.C. and Sofamor Danek Group. Inc.,* No. 4:96CV177–H1, Judgment and Order (E.D.N.C., Howard, J., Sept. 10, 1998); Second Addendum Defs.' Br. Supp. Mot. Summ. J.—*Jimmy R. Kirkman,* slip op. (July 21, 1998); First Addendum Defs.' Br. Supp. Mot. Summ. J.—*Diana L. Fender,* slip op. (July 21, 1998); Third Addendum Defs.' Br. Supp. Mot. Summ. J.—*Carl E. Swann v. Sofamor, S.N.C. and Sofamor Danek Group, Inc.,* 1:98CV100, Memorandum and Order (W.D.N.C., Thornburg, J., July 21, 1998).[8]

C. Defendants are entitled to summary judgment on Plaintiff's claim for negligent infliction of emotional distress.

***5** In order to establish a prima facie case of negligent infliction of emotional distress Plaintiff must prove the following three elements: "1) the defendant negligently engaged in conduct, 2) it was reasonably foreseeable that such conduct would cause the plaintiff severe emotional distress ..., and 3) the conduct did in fact cause the plaintiff severe emotional distress."*Johnson v. Ruark Obstetrics,* 327 N.C. 283, 304, 395 S.E.2d 85, 97,*reh'g denied,*327 N.C. 644, 399 S.E.2d 133 (1990).

It is well settled in North Carolina that Plaintiff must introduce medical documentation of the alleged severe emotional distress. *See**Waddle v. Sparks,* 331 N.C. 73, 85, 414 S.E.2d 22, 28 (1992); *see also* Third Addendum Defs.' Br. Supp. Mot. Summ. J. *Carl E. Swann,* slip. op. at 9 (July 21, 1998) (Granting summary judgment for Defendants on the issue of negligent infliction of emotional distress where "Plaintiff ... failed to make any forecast of admissible medical documentation.") In the absence of expert testimony showing that Defendants' actions caused Plaintiff severe emotional distress, Defendants' motion for summary judgment on this issue should be granted.

D. Plaintiff's claim for fraud on the FDA fails as a matter of law.

In North Carolina a claim for fraud requires proof of the following elements: " '(1) False representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party." ' *Rowan County Bd. Of Educ. v. United States Gypsum Co.,* 332 N.C. 1, 17, 418 S.E.2d 648, 658 (1992) (citations omitted). Having already determined that Plaintiff has not established causation and the existence of any defect in her instrumentation, Plaintiff's fraud claim must also fail. Since Plaintiff cannot prove that she was damaged by the Defendants' internal fixation device, she cannot prove that she has been damaged by any false statements and omissions allegedly made by Defendants. Therefore, Defendants' motion for summary judgment on Plaintiff's claim for fraud is granted. [9]

E. Defendants are entitled to summary judgment on Plaintiff's breach of express warranty claim.

With regard to the remaining causes of action lodged against Defendants, all claims based upon breach of express warranty were dismissed by Judge Bechtle in MDL 1014, except as to those plaintiffs who could show good cause why the order should not apply to them. *In re: Orthopedic Bone Screw Prods. Liability Litig.,* MDL No. 1014, 1996 WL 900339 (E.D.Pa. Dec. 3, 1996)(Pretrial Order No. 651)(Requiring a plaintiff to 1) identify a specific express warranty made by the manufacturer of the bone screw implanted in a plaintiff prior to the plaintiff's fusion surgery, 2) describe how the plaintiff or the plaintiff's surgeon relied on the warranty, and 3) specifically describe how the warranty was breached in order to establish good cause as to why a plaintiff should not be bound by the court order.); Fourth Addendum Defs.' Br. Supp. Mot. Summ. J.—*Geneva T. Hill,* slip op. at 12 (Sept. 10, 1998); Second Addendum Defs.' Br. Supp. Mot. Summ. J.—*Jimmy R. Kirkman,* slip op. at 8 (July 21, 1998); First Addendum Defs. Br. Supp. Mot. Summ. J.—*Diana L. Fender,* slip op. at 9 (July 21, 1998)(Granting summary judgment on Plaintiff's breach of express warranty claim in light of Judge Bechtle's earlier dismissal of the cause of action.) Because the court finds that Plaintiff has failed to introduce any evidence establishing why she should not be bound by Judge Bechtle's court order, summary judgment on this claim is appropriate.

F. Plaintiff's claim for punitive damages fails as a matter of law.

***6** Because this court finds that Defendants are entitled to summary judgment on all five causes of action, Plaintiff's derivative claim for punitive damages necessarily fails as well. *See* Fourth Addendum Defs.' Br. Supp. Mot. Summ. J.*Geneva T. Hill,* slip op. at 13 (Sept. 9, 1998) (Holding that "as the punitive damages claim ... [is] purely derivative" that claim fails.); *see also**Paris v. Kreitz,* 75 N.C.App. 365, 377, 331 S.E.2d 234, 243,*disc. rev. denied,*315 N.C. 185, 337 S.E.2d 858 (1985). Therefore, Defendants are entitled to summary judgment on Plaintiff's claim for punitive damages.

III. CONCLUSION

For the reasons stated above, Defendants' motion for summary judgment [14] on all claims by Plaintiff against them is granted.

An Order and Judgment in accordance with this memorandum opinion shall be filed contemporaneously herewith.

Footnotes

1 Plaintiff filed an amended complaint on November 27, 1996, which supersedes the original complaint and abandons claims for negligence per se and negligent misrepresentation. The amended complaint alleges five causes of action which include: negligence, breach of implied warranty, breach of express warranty, negligent infliction of emotional distress, and fraud. (Mem. Supp. Defs.' Mot. Summ. J. at 3.)

2 Because Plaintiff's original attorney was permitted to withdraw, Plaintiff is proceeding pro se. By letter from the clerk of court, dated December 4, 1998, Plaintiff was notified that she had 20 days to respond to Defendants' Motion for Summary Judgment. *See* December 4, 1998 letter, stating:

> [F]ailure to respond, or file evidence in rebuttal within the allowed time may cause the court to conclude that the defendants' contentions are undisputed and/or that you no longer wish to pursue the matter. Therefore, unless you file a response in opposition to the defendants' motion, it is likely a motion for summary judgment will be granted in favor of the defendant[s]."

Plaintiff responded by a handwritten note. While Plaintiff technically has not complied with the formal requirements for responding to a motion for summary judgment, in light of Plaintiff's pro se status, the court will treat Plaintiff's note as a response for purposes of ruling on Defendants' motion.

3 Although a narrow exception to the general rule requiring expert testimony as to causation in back injury cases exists, it is inapplicable to the case at hand. *See* *Click v. Pilot Freight Carriers, Inc.*, 300 N.C. 164, 168, 265 S.E.2d 389, 391 (1980) (Finding expert medical testimony unnecessary only in uncomplicated situations where "the plaintiff was theretofore in good health and free from any disability of the kind involved.").

4 Moreover, even Plaintiff admits that she does not know the cause of her alleged injuries. (Mem. Supp. Defs.' Mot. Summ. J., Ex.1 -Lester Dep. at 88.)

5 *See* Mem. Supp. Defs.' Mot. Summ. J., Ex. 2—Grubb Dep. at 24.

6 Dr. Grubb also testified that "[t]here is no question that [the use of bone screws and the pedicles] is safe and effective. In fact, it is by far the safest of all the instrumentation techniques that we've used in the lumbar spine."(Mem. Supp. Defs.' Mot. Summ. J., Ex. 2—Grubb Dep. at 14.)

7 Plaintiff's failure to warn claims include her fraud, negligence and breach of warranty claims. (Mem. Supp. Defs.' Mot. Summ. J. at 12.)

8 The cases were filed by Defendants as suggestions of subsequently decided controlling authority. *See* First, Second, Third and Fourth Addendum Defs.' Br. Supp. Mot. Summ. J.

9 The court takes notice of the fact that while Judge Bechtle had earlier ruled that no private right of action exists under the FDA, the Third Circuit recently reversed the decision. *See* *In re: Orthopedic Bone Screw Prods. Liability Litig.*, 1998 WL 793200, at * 6–10 (3rd Cir. Nov. 17, 1998), *petition for rehearing filed* (Dec. 1, 1998) (Holding that federal law does not preempt a private right of action.). Since the Third Circuit opinion is not binding and alternative grounds exist for disposing of Plaintiff's fraud claim, the court renders no opinion as to whether North Carolina courts would recognize such a cause of action.

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United States District Court,
M.D. North Carolina.

John K. McCAULEY, Plaintiff,
v.
HOSPIRA, INC. and APP Pharmaceuticals, LLC, Defendants.

No. 1:11CV108. | Aug. 5, 2011.

Attorneys and Law Firms

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ORDER AND MEMORANDUM OPINION AND RECOMMENDATION

WALLACE W. DIXON, United States Magistrate Judge.

***1** This matter is before the court on Defendant Hospira, Inc.'s ("Hospira") motion to partially dismiss Plaintiff's First Amended Complaint pursuant to Rules 12(b)(6), 8(a)(2), and 9(b) of the Federal Rules of Civil Procedure and Local Rule 7.3 for failure to state a claim upon which relief can be granted [docket no. 18]. Defendant APP Pharmaceuticals, LLC's ("APP") motion to join Defendant Hospira's motion to dismiss [docket no. 21] is also pending. The parties have either responded to the respective motions, or the time to do so has passed, and the matter is ripe for disposition. The parties have not consented to the jurisdiction of the magistrate judge; therefore, the motion to dismiss must be dealt with by way of recommendation. There is no opposition to APP's motion to join Hospira's motion to dismiss; accordingly, the court will grant this motion. For the reasons discussed herein, it will be recommended that the court deny Defendants' motions to dismiss Counts 1, 2, and 6 of Plaintiff's First Amended Complaint and grant Defendants' motion to dismiss Counts 5 and 7.

BACKGROUND

Plaintiff John K. McCauley, a resident of North Carolina, brought this diversity action seeking to hold liable APP and Hospira for injuries allegedly caused by Plaintiff's use of Defendants' pharmaceutical drug. (Am.Compl.¶ 43). According to the amended complaint, Defendants are both "generic drug manufacturers and manufacture and market a generic form of vancomycin[1] in various dosages."(*Id.* ¶ 25). Plaintiff was allegedly administered Defendants' vancomycin products at Duke Hospital in Durham, North Carolina between January 15, 2008, and February 11, 2008. (*Id.* ¶ 41). Plaintiff allegedly developed "life threatening condition[s] ... which necessitated prolonged hospitalization and continued medical care and treatment."(*Id.* ¶ 43).

Plaintiff asserts claims of products liability due to defective design or defect (Count 1), products liability due to failure to warn (Count 2), negligence (Count 3), violation of the North Carolina Unfair and Deceptive Trade Practices Act (Count 4), common law misrepresentation and concealment (Count 5), breach of implied warranties (Count 6), and breach of express warranties (Count 7). Defendant Hospira, joined by Defendant APP, has filed a motion to dismiss Counts 1–2 and 5–7.

STANDARD OF REVIEW

The purpose of a motion to dismiss for failure to state a claim under FED.R.CIV.P. 12(b)(6)) is to test the sufficiency of the complaint-not to decide the merits of the action. *Schatz v. Rosenberg,* 943 F.2d 485, 489 (4th Cir.1991); *Food Lion, Inc. v. Capital Cities/ABC, Inc.,* 887 F.Supp. 811, 813 (M.D.N.C.1995). Generally, the court looks only to the complaint itself to ascertain the propriety of a motion to dismiss. *See George v. Kay,* 632 F.2d 1103, 1106 (4th Cir.1980). At this stage of litigation, a plaintiff's well-pleaded allegations are taken as true; and the complaint, including all reasonable inferences therefrom, are liberally construed in the plaintiff's favor. *McNair v. Lend Lease Trucks, Inc.,* 95 F.3d 325, 327 (4th Cir.1996).

***2** A plaintiff need not plead detailed evidentiary facts, but he must give each defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. *See Bolding v. Holshouser,* 575 F.2d 461, 464 (4th

Cir.1978). This duty of fair notice under Rule 8(a) requires the plaintiff to allege, at a minimum, the necessary facts and grounds that will support his right to relief. *See Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555 (2007).

A plaintiff "fails to state a claim upon which relief may be granted,"28 U.S.C. § 1915A(b)(1), when the complaint does not "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."*Ashcroft v. Iqbal,* 129 S.Ct. 1937, 1949 (2009) (emphasis added) (internal citations omitted) (quoting *Twombly,* 550 U.S. at 570)."Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.' " *Id.* (quoting *Twombly,* 550 U.S. at 557 (internal quotations omitted)).

This standard under Rule 8"demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation."*Id.*"A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertions' devoid of 'further factual enhancement.' " *Id.* (internal brackets and citations omitted) (quoting *Twombly,* 550 U.S. at 555, 557). In other words, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Finally, in evaluating a complaint, the court may anticipate affirmative defenses which are clear on the face of the complaint. *Todd v. Baskerville,* 712 F.2d 70 (4th Cir.1983); *Nasim v. Warden, Md. House of Corr.,* 64 F.3d 951, 954 (4th Cir.1995) (en banc) (stating that a court may apply common sense and reject fantastic allegations and/or rebut them with judicially noticed facts). With these principles in mind, the court turns now to the motion to dismiss.

DISCUSSION

1. Defective Design and Failure to Warn (Counts 1 and 2 of First Amended Complaint)

In Count 1 of his First Amended Complaint, Plaintiff alleges that Defendants are responsible for his injuries resulting from his use of their vancomycin products because those products were defective. (Am.Compl.¶¶ 44–55). In Count 2, Plaintiff alleges Defendants are responsible for his injuries because they failed to warn Plaintiff, his physician, and the public of the dangers associated with vancomycin products. (*Id.* ¶¶ 56–68). In brief, Plaintiff alleges that Defendants disregarded numerous medical studies which "documented that vancomycin has a proven risk of inducing adverse reactions to the skin and tissues, which are known in the scientific community as SCAR events (severe cutaneous adverse reactions)."(*Id.* ¶ 32).

***3** Hospira, joined by APP, argues that Counts 1 and 2 are strict products liability claims prohibited by North Carolina law. According to Defendants, "[b]ecause Counts 1 and 2 are 'brought for or on account of personal injury' and allege that vancomycin was 'defective' and/or 'unreasonably dangerous,' " they are solely claims of strict products liability. (Mem. in Supp. of Mot. to Dismiss 7). North Carolina does not recognize strict liability in products liability actions. *See, e.g.,*N.C. GEN.STAT. § 99B–1.1; *Smith v. Fiber Controls Corp.,* 300 N.C. 669, 678, 268 S .E.2d 504, 509–10 (1980); *Stoddard v. Wyeth, Inc.,* 630 F.Supp.2d 631 (E.D.N.C.2009).

In Counts 1 and 2 of his First Amended Complaint, Plaintiff alleges that Defendants are liable for his injuries resulting from his use of their vancomycin product(s) based on the defective design of the product(s) and the Defendants' failure to warn of the dangers of the product(s). While these allegations could be construed as asserting a claim for strict liability, Plaintiff also alleges facts and/or reaches factual conclusions that, if true, support products liability claims under a negligence theory. Under North Carolina law, a products liability action based upon negligence requires the plaintiff to prove the following elements: (1) duty; (2) breach; (3) causation; and (4) damages. *Bryant v. Adams,* 116 N.C. Ct.App. 448, 465, 448 S.E.2d 832 (1994); *Smith v. Wyeth–Ayerst Labs. Co.,* 278 F.Supp.2d 684, 706 (W.D.N.C.2003).*See*N.C. GEN.STAT. § 99B-(6)(a). A duty to warn arises when the supplier of a product knows or has reason to know that the product is, or can be, dangerous for the use for which it is supplied. *Stegall v. Catawba Oil Co.,* 260 N.C. 459, 133 S.E.2d 138 (1963).

Allegations that a product is "defective" or "unreasonably dangerous" may be legal conclusions insufficient to support a claim for relief. The factual allegations and conclusions underlying them, however, are not. For example, Plaintiff here "alleg[es] that vancomycin was defective because 'it had a negative risk-benefit profile as to certain patient populations, or for certain uses.' " (Am.Compl.¶¶ 52–54). Even if the allegation that

vancomycin is defective is a legal conclusion that cannot support a claim for relief, the allegation that vancomycin had a negative risk-benefit profile is a factual allegation that may prove that the manufacturer acted unreasonably, as required for products liability claims under N.C. GEN.STAT. §§ 99B–5 and 99B–6. Similarly, allegations of "numerous labeling defects"—such as the label's lack of a warning about the risk of adverse reactions—if true, plausibly support a products liability claim under a negligence standard. (Am.Compl.¶¶ 58–67). Plaintiff has thus stated claims for products liability under North Carolina law, and Defendants' motion should be denied as to Counts 1 and 2.

2. Breach of Implied Warranty (Count 6 of First Amended Complaint)

***4** In Count 6, Plaintiff alleges that Defendants breached implied warranties. North Carolina law provides for claims of breach of implied warranties under three statutes: N.C. GEN.STAT. § 99B–1 .2. Breach of warranty (as a products liability action); N.C. GEN.STAT. § 25–2–314. Implied warranty: Merchantability; usage of trade (as a North Carolina Uniform Commercial Code action); and N.C. GEN.STAT. § 25–2–315. Implied warranty: Fitness for particular purpose (as a North Carolina Uniform Commercial Code action)."An action for breach of implied warranty of merchantability [and, presumably, an action for breach of implied warranty of fitness for a particular purpose] ... 'is a "products liability action" within the meaning of the Products Liability Act if ... the action is for injury to [a] person ... resulting from a sale of a product.' " *DeWitt v. Eveready Battery Co.,* 355 N.C. 672, 682–83, 565 S.E.2d 140, 147 (2002) (quoting *Morrison v. Sears, Roebuck & Co.,* 319 N.C. 298, 303, 304, 354 S.E.2d 495, 498, 499 (1987)).

North Carolina common law generally requires privity of contract in order to assert an implied warranty claim. *Kelly v. Georgia–Pacific LLC,* 671 F.Supp.2d 785, 796 (E.D.N.C.2009) (citing *Terry v. Double Cola Bottling Co.,* 263 N.C. 1, 3, 138 S.E.2d 753, 754 (1964)). In certain situations, however, privity is not required. Under the North Carolina Products Liability Act, there is no privity requirement for implied warranty claims when an action is "brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture ... of any product."N.C. GEN STAT. § 99B–1(3)."A claimant who is a buyer, as defined in the Uniform Commercial Code, of the product involved, or who is a member or a guest of a member of the family of the buyer, a guest of the buyer, or an employee of the buyer may bring a products liability action directly against the manufacturer of the product involved for breach of implied warranty; and the lack of privity of contract shall not be grounds for the dismissal of such action."N.C. GEN.STAT. § 99B–2(b). Because Plaintiff alleges personal injuries—as opposed to solely economic loss—his claim is a products liability action subject to the lessened privity requirements of N.C. GEN.STAT. § 99B–2(b).*See Gregory v. Atrium Door & Window Co.,* 106 N.C. Ct.App. 142, 144, 415 S.E.2d 574, 575 (1992).

Defendant Hospira, joined by Defendant APP, argues that Plaintiff fails to state a claim for breach of implied warranty under North Carolina law because Plaintiff does not allege that he is a "buyer" and, furthermore, because Plaintiff does not—and cannot—meet even the lessened privity requirements defined above. (Reply 2 [docket no. 28]). Under North Carolina's Uniform Commercial Code, " '[b]uyer' means a person who buys or contracts to buy goods."N.C. GEN.STAT. § 25–2–103. In his amended complaint—though not necessarily in the section pertaining to Count 6—Plaintiff alleges that "[t]he Plaintiff purchased and used Vancomycin for personal, family or household purposes."(Am.Compl.¶ 87). Plaintiff thus alleges facts supporting a claim that he is a buyer, as defined by the North Carolina Uniform Commercial Code. Furthermore, case law does not preclude Plaintiff from arguing—based on facts alleged in his first amended complaint—that he meets the requirements of one of the other listed categories of claimants.

***5** Plaintiff's allegation that he purchased vancomycin is thus a plausible, factual allegation that Plaintiff is a "buyer." Plaintiff has pleaded sufficient facts to state a claim for breach of implied warranty under North Carolina law. Defendants' motion to dismiss should be denied as to Count 6.

3. Fraudulent Concealment and Misrepresentation Claim (Count 5)

In Count 5 of his amended complaint, Plaintiff alleges fraudulent concealment and misrepresentation on the part of Defendants. Plaintiff alleges that Defendants had a duty to disclose pertinent information about vancomycin and that they made false representations and/or failed to disclose information about the risks associated with the use of vancomycin.

Under North Carolina law, Plaintiff must allege that Defendants made a misrepresentation to Plaintiff and that Plaintiff relied upon that misrepresentation to his detriment. *Wilson v. Dryvit Sys., Inc.,* 206 F.Supp.2d 749, 755 (E.D.N.C.2002); *Ragsdale v. Kennedy,* 286 N.C. 139,

138, 209 S.E.2d 494, 500 (1974). More specifically, "[t]he essential elements of fraud are: (1)[f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party."*Wilson,* 206 F.Supp.2d at 755; *Rowan County Bd. of Educ. v. U.S. Gypsum Co.,* 332 N.C. 1, 17, 418 S.E.2d 648, 658 (1992).

Defendants have moved to dismiss Count 5 for failure to comply with the particularity requirement of Rule 9(b) of the Federal Rules of Civil Procedure. Under Rule 9(b), "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."FED.R.CIV.P. 9(b). The particularity element requires that a plaintiff plead the "time, place, and contents of the alleged fraudulent representation, as well as the identity of each person making the misrepresentation and what was obtained thereby."*Liner v. DiCresce,* 905 F.Supp. 280, 287 (M.D.N.C.1994). Moreover, "where there are multiple defendants, plaintiffs must allege all claims with particularity as to each defendant."*Dealers Supply Co., Inc. v. Cheil Indus., Inc.,* 348 F.Supp.2d 579, 589 (M.D.N.C.2004).

The amended complaint in this matter contains assertions that (1) "[d]efendants had a duty to fully and accurately disclose all material facts regarding the risks and benefits of vancomycin products to plaintiff and his prescribing physician;" (2) "[d]efendants made representations and failed to disclose" relevant information and that "[d]efendants knew or should have known at the time [of the representations] that their representations were false and fraudulent regarding the dangers and risk of adverse health events associated with use of vancomycin;" (3) these "fraudulent misrepresentations and omissions were made knowingly, intentionally, and with the intent of defrauding and deceiving the medical community, plaintiff and the public;" (4) "[d]efendants' fraudulent misrepresentations intentionally concealed ... material information" of "statistically significant risk[s]" associated with vancomycin, risks which were available in scientific literature "of which defendants were or should have been aware ...;" and (5) "[p]laintiff and his prescribing doctor had no knowledge of the falsity of defendants['] actions and believed this drug to be safe for its intended use." (Am.Compl.¶¶ 95–101.) Because these allegations fail to set forth specific and particular facts concerning Defendants' alleged misrepresentations, they are insufficient to satisfy the requirements of Rule 9(b). Moreover, the allegations are not asserted with particularity as to each defendant; rather, the allegations in the amended complaint refer to Defendants collectively. As such, the allegations are not sufficient under Rule 9(b).

***6** A fraud claim based solely on a purported misrepresentation to a third party, moreover, must fail as a matter of law. *Wilson,* 206 F.Supp. at 755 ("The court has been unable to find any North Carolina cases in which a plaintiff has been permitted to recover on a fraud claim for misrepresentations that were made to third parties ."). As Defendants point out, Plaintiff does not allege that Defendants made any oral or written misrepresentations directly to Plaintiff. Rather, Plaintiff claims that Hospira made statements to "prescribing physicians and consumers" about "the dangers and risks of adverse health events associated with the use of vancomycin" (Am.Compl.¶ 96) and that Defendants' "fraudulent misrepresentations intentionally concealed" various safety issues with regard to the use of vancomycin. (*Id.* ¶ 98). As such, Plaintiff has failed to state a claim for misrepresentations made to third parties.

4. Breach of Express Warranty Claim (Count 7)

In order to recover for a breach of express warranty under state or federal law, a plaintiff must allege that a defect exists, that a warranty covered the item, and that the seller breached the warranty. N.C. GEN.STAT. § 25–2–313 (2007); 15 U.S.C. § 2310(d); *see also Harbor Point Homeowners' Ass'n, Inc. v. DJF Enter., Inc.,* 697 S.E.2d 439, 447 (N.C.Ct.App.2010). An express warranty is defined as "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain...."N.C. GEN.STAT. § 25–2–313.

In Count 7 of the amended complaint, Plaintiff alleges that "Defendants' [sic] expressly warranted that Vancomycin drug products were safe and effective" (Am.Comp.¶ 110), that Plaintiff and his doctors relied on these warranties (*Id.* ¶ 111), that the express warranty "failed to disclose design, manufacturing and safety defects inherent in Vancomycin"(*Id.* ¶ 112) and that Defendants breached these warranties when they continued to market and sell Vancomycin while they "knew of the design, manufacturing and safety defects and the risk[s]" described in the complaint (*Id.* ¶ 113). These "naked assertions" are "devoid of further factual enhancement." *Twombly,* 550 U.S. at 557. Plaintiff has failed to identify any specific words, promises, affirmations, or statements made by Hospira or APP to Plaintiff or his physicians that would create an express warranty. Plaintiff does not further address the alleged express warranty or its contents and does not address at all how the warranty was made, to whom it was made, or any other details with regard to the alleged warranty. This

conclusory recitation of the elements of a breach of warranty claim is simply insufficient to state a claim for breach of express warranty, and Defendants' motion to dismiss should be granted as to Count 7.

CONCLUSION

For the reasons stated, Defendant APP's motion to join Defendant Hospira's motion to dismiss [docket no. 21] is **GRANTED.**Furthermore, **IT IS RECOMMENDED** that the motion to dismiss Counts 1, 2, and 6 of Plaintiff's First Amended Complaint be **DENIED** and that the motion to dismiss Counts 5 and 7 [docket no. 18] be **GRANTED.**

Parallel Citations

75 UCC Rep.Serv.2d 224

Footnotes

1 As alleged in the complaint, vancomycin is an antibiotic drug that is used to treat infections. (Am.Compl.¶ 18).

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